EXHIBIT B

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, 423, 424, 425, and 455

[CMS–1770–F, CMS–1751–F2, CMS–1744–F2, CMS–5531–IFC]

RINs 0938–AU81, 0938–AU95, 0938–AU31, 0938–AU32

Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID–19 Interim Final Rules

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Final rule and interim final rules.

SUMMARY: This major final rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare and Medicaid provider enrollment policies, including for skilled nursing facilities; updates to conditions of payment for DMEPOS suppliers; HCPCS Level II coding and payment for wound care management products; electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act); updates to the Medicare Ground Ambulance Data Collection System; provisions under the Infrastructure Investment and Jobs Act; and finalizes the CY 2022 Methadone Payment Exception for Opioid Treatment Programs IFC. We are also finalizing, as implemented, a few provisions included in the COVID–19 interim final rules with comment period.

DATES: These regulations are effective on January 1, 2023.

FOR FURTHER INFORMATION CONTACT: *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for any issues not identified below. Please indicate the specific issue in the subject line of the email.

Michael Soracoe, (410) 786–6312, for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Kris Corwin, (410) 786–8864, for issues related to the comment solicitation on strategies for updates to practice expense data collection and methodology.

Sarah Leipnik, (410) 786–3933, and Anne Blackfield, (410) 786–8518, for issues related to the comment solicitation on strategies for improving global surgical package valuation.

Larry Chan, (410) 786–6864, for issues related to potentially misvalued services under the PFS.

Kris Corwin, (410) 786–8864, Patrick Sartini, (410) 786–9252, and Larry Chan, (410) 786–6864, for issues related to telehealth services and other services involving communications technology.

Regina Walker-Wren, (410) 786–9160, for issues related to nurse practitioner and clinical nurse specialist certification by the Nurse Portfolio Credentialing Center (NPCC).

Lindsey Baldwin, (410) 786–1694, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to PFS payment for behavioral health services.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to PFS payment for evaluation and management services.

Geri Mondowney, (410) 786–1172, Morgan Kitzmiller, (410) 786–1623, Julie Rauch, (410) 786–8932, and Tamika Brock, (312) 886–7904, for issues related to malpractice RVUs and geographic practice cost indices (GPCIs).

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to non-face-to-face nonphysician services/remote therapeutic monitoring services (RTM).

Zehra Hussain, (214) 767–4463, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to payment of skin substitutes.

Pamela West, (410) 786–2302, for issues related to revisions to regulations to allow audiologists to furnish diagnostic tests, as appropriate without a physician order.

Emily Forrest, (410) 786–8011, Laura Ashbaugh, (410) 786–1113, Anne Blackfield, (410) 786–8518, and Erick Carrera, (410) 786–8949, for issues related to PFS payment for dental services.

Heidi Oumarou, (410) 786–7942, for issues related to the rebasing and revising of the Medicare Economic Index (MEI).

Laura Kennedy, (410) 786–3377, Adam Brooks, (202) 205–0671, and Rachel Radzyner, (410) 786–8215, for issues related to requiring manufacturers of certain single-dose container or single-use package drugs payable under Medicare Part B to provide refunds with respect to discarded amounts.

Laura Ashbaugh, (410) 786–1113, and Rasheeda Arthur, (410) 786–3434, for issues related to Clinical Laboratory Fee Schedule.

Lisa Parker, (410) 786–4949, or *FQHC-PPS@cms.hhs.gov*, for issues related to FQHCs.

Michele Franklin, (410) 786–9226, or *RHC@cms.hhs.gov*, for issues related to RHCs.

Daniel Feller, (410) 786–6913, and Elizabeth Truong (410) 786–6005, for issues related to coverage of colorectal cancer screening.

Heather Hostetler, (410) 786–4515, for issues related to removal of selected national coverage determinations.

Lindsey Baldwin, (410) 786–1694, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs.

Sabrina Ahmed, (410) 786–7499, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality performance standard and quality reporting requirements.

Aryanna Abouzari, (415) 744–3668, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to the Shared Savings Program burden reduction proposal on OHCAs.

Janae James, (410) 786–0801, or Elizabeth November, (410) 786–4518, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to Shared Savings Program beneficiary assignment and financial methodology.

Lucy Bertocci, (410) 786–4008, or *SharedSavingsProgram@cms.hhs.gov*, for inquiries related to Shared Savings Program advance investment payments, participation options and burden reduction policies.

Rachel Radzyner, (410) 786–8215, and Michelle Cruse, (443) 478–6390, for issues related to vaccine administration services.

Katie Parker, (410) 786–0537, for issues related to medical necessity and documentation requirements for nonemergency, scheduled, repetitive ambulance services.

Frank Whelan, (410) 786–1302, for issues related to Medicare provider

enrollment regulation updates (including for skilled nursing facilities), State options for implementing Medicaid provider enrollment affiliation provisions, and conditions of payment for DMEPOS suppliers.

Mei Zhang, (410) 786–7837, and Kimberly Go, (410)786–4560, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan (section 2003 of the SUPPORT Act).

Amy Gruber, (410) 786–1542, or *AmbulanceDataCollection@cms.hhs.gov*, for issues related to the Medicare Ground Ambulance Data Collection System and Ambulance Fee Schedule (AFS).

Sundus Ashar, *Sundus.ashar1@cms.hhs.gov*, for issues related to HCPCS Level II Coding for skin substitutes.

Renee O'Neill, (410) 786–8821, or Kati Moore, (410) 786–5471, for inquiries related to Merit-based Incentive Payment System (MIPS).

Richard Jensen, (410) 786–6126, for inquiries related to Alternative Payment Models (APMs).

Lindsey Baldwin, (410) 786–1694 for inquiries related to Opioid Treatment Programs: CY 2022 Methadone Payment Exception.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

This major final rule revises payment polices under the Medicare PFS and makes other policy changes, including to the implementation of certain provisions of the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022), Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, December 10, 2021), Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021), Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment. In addition, this major final rule includes provisions regarding other Medicare payment policies described in sections III. and IV.

B. Summary of the Major Provisions

The statute requires us to establish payments under the PFS, based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE), and malpractice (MP) expense. In addition, the statute requires that each year we establish, by regulation, the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major final rule, we are establishing RVUs for CY 2023 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This final rule also includes discussions and provisions regarding several other Medicare Part B payment policies.

Specifically, this final rule addresses:

- Determination of PE RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (section II.D.)
- Valuation of Specific Codes (section II.E.)
- Evaluation and Management (E/M) Visits (section II.F.)
- Geographic Practice Cost Indices (GPCI) (section II.G.)
- Determination of Malpractice Relative Value Units (RVUs) (section II.H.)
- Non-Face-to-Face/Remote Therapeutic Monitoring (RTM) Services (section II.I.)
- Payment for Skin Substitutes (section II.J.)
- Provision to Allow Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order (section II.K.)
- Provisions on Medicare Parts A and B Payment for Dental Services (section II.L.)
- Rebasing and Revising the Medicare Economic Index (MEI) (section II.M.)
- Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts (§§ 414.902 and 414.940) (section III.A.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)
- Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions, and Policies for Specimen Collection Fees and Travel Allowance for Clinical Diagnostic Laboratory Tests (section III.C.)
- Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers (section III.D.)
- Removal of Selected National Coverage Determinations (section III.E.)
- Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.F.)
- Medicare Shared Savings Program (section III.G.)
- Medicare Part B Payment for Preventive Vaccine Administration Services (section III.H.)
- Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services (section III.I.)
- Medicare Provider and Supplier Enrollment and Conditions of DMEPOS Payment (section III.J.)
- State Options for Implementing Medicaid Provider Enrollment Affiliation Provision (section III.K.)
- Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD Plan (section 2003 of the SUPPORT Act) (section III.L.)
- Medicare Ground Ambulance Data Collection System (GADCS) (section III.M.)
- Revisions to HCPCS Level II Coding Procedures for Skin Substitutes Products (section III.N.)
- Updates to the Quality Payment Program (section IV.)
- Opioid Treatment Programs: CY 2022 Methadone Payment Exception and Origin and Destination Requirements Under the Ambulance Fee Schedule (section V.A.)
- Finalizing provisions from the Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency (CMS–1744–IFC) (Section V.B.)
- Finalizing provisions from the Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program (CMS–5531–IFC) (Section V.C.)
- Collection of Information Requirements (section VI.)
- Regulatory Impact Analysis (section VII.)

3. Summary of Costs and Benefits

We have determined that this final rule is economically significant. For a detailed discussion of the economic

impacts, see section VII., Regulatory Impact Analysis, of this final rule.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service specific PE RVUs. We refer readers to the CY 2010 Physician Fee Schedule (PFS) final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked, in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty that was obtained from the AMA's SMS. The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2023 PFS final rule PE/HR'' on the CMS website under downloads for the CY 2023 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the

indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Then, we incorporate the specialty specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: a professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we direct readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2023 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. This file contains a table that illustrates the calculation of PE RVUs as described in this final rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting

the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert interested parties. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other interested parties on changes to this list on an annual basis. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 52983) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

We did not make any proposals associated with the list of expected specialty assignments for low volume services, however we received public comments on this topic from interested parties. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they had performed an analysis to identify all codes that meet the criteria to receive a specialty override under this CMS policy and drafted updated recommendations for CY 2023. Commenters stated that the purpose of assigning a specialty to these codes was to avoid the major adverse impact on MP RVUs that result from errors in specialty utilization data magnified in representation (percentage) by small sample size. These commenters submitted a list of several dozen low volume HCPCS codes with recommended expected specialty assignments.

Response: After reviewing the information provided by the commenters to determine that the submitted specialty assignments were appropriate for the service in question, we are finalizing the additions in Table 1 to the list of expected specialty assignments for low volume services.

BILLING CODE 4150–28–P

TABLE 1: New Additions to Expected Specialty Assignment List

HCPCS	Short Descriptor	Expected Specialty Assignment
15650	Transfer skin pedicle flap	Plastic and Reconstructive Surgery
15787	Abrasion lesions add-on	Internal Medicine
20705	Rmvl i-artic rx delivery dev	Orthopedic Surgery
21070	Remove coronoid process	Otolaryngology
21336	Open tx septal fx w/wo stabj	Otolaryngology
21440	Treat dental ridge fracture	Maxillofacial Surgery
23031	Drain shoulder bursa	Orthopedic Surgery
24160	Remove elbow joint implant	Orthopedic Surgery
24620	Treat elbow fracture	Orthopedic Surgery
26685	Treat hand dislocation	Hand Surgery
26705*	Treat knuckle dislocation	Orthopedic Surgery
26706	Pin knuckle dislocation	Hand Surgery
27448	Incision of thigh	Orthopedic Surgery
28405	Treatment of heel fracture	Orthopedic Surgery
31090	Exploration of sinuses	Otolaryngology
31643	Diag bronchoscope/catheter	Pulmonary Disease
31661	Bronch thermoplsty 2/> lobes	Pulmonary Disease
31830	Revise windpipe scar	Otolaryngology
33370*	Tcat plmt&rmvl cepd perq	Cardiology
33406	Replacement aortic valve opn	Thoracic Surgery
33894*	Evasc st rpr thrc/aa acrs br	Cardiology
33895*	Evasc st rpr thrc/aa x crsg	Cardiology
33897*	Perq trluml angp nt/recr coa	Cardiology
33997*	Rmvl perq right heart vad	Cardiology
34702	Evasc rpr a-ao ndgft rpt	Vascular Surgery
35587	Vein byp pop-tibl peroneal	Vascular Surgery
41114	Excision of tongue lesion	Otolaryngology
41153	Tongue mouth neck surgery	Otolaryngology
43112	Esphg tot w/thrcm	Thoracic Surgery
43770	Lap place gastr adj device	General Surgery
43880	Repair stomach-bowel fistula	General Surgery
45392	Colonoscopy w/endoscopic fnb	Gastroenterology
52327	Cystoscopy inject material	Urology
52400	Cystouretero w/congen repr	Urology
53665	Dilation of urethra	Urology
58140	Myomectomy abdom method	Obstetrics/Gynecology
58670	Laparoscopy tubal cautery	Obstetrics/Gynecology
59320	Revision of cervix	Obstetrics/Gynecology
61316	Implt cran bone flap to abdo	Neurosurgery
64583	Rev/rplct hpglsl nstm ary pg	Otolaryngology
64584	Rmvl hpglsl nstim ary pg	Otolaryngology
64834	Repair of hand or foot nerve	Hand Surgery
66720	Destruction ciliary body	Ophthalmology
67570	Decompress optic nerve	Ophthalmology
67902	Repair eyelid defect	Ophthalmology
68510	Biopsy of tear gland	Ophthalmology
69661	Revise middle ear bone	Otolaryngology
69716	Impltj oi implt skl tc esp	Otolaryngology
69719	Revj/rplcmt oi implt tc esp	Otolaryngology
69726	Rmvl oi implt skl perq esp	Otolaryngology
69727	Rmvl oi implt skl tc esp	Otolaryngology
77790	Radiation handling	Radiation Oncology
78660	Nuclear exam of tear flow	Nuclear Medicine
90956	Esrd srv 1 visit p mo 2-11	Nephrology
91113	Gi trc img intral colon i&r	Gastroenterology

HCPCS	Short Descriptor	Expected Specialty Assignment
92230	Eye exam with photos	Ophthalmology
93319	3d echo img cgen car anomal	Cardiology
94610	Surfactant admin thru tube	Pediatric Medicine
94625	Phy/qhp op pulm rhb w/o mntr	Pulmonary Disease
95958	Eeg monitoring/function test	Neurology
0446T	Insj impltbl glucose sensor	Endocrinology
0447T	Rmvl impltbl glucose sensor	Endocrinology
0448T	Remvl insj impltbl gluc sens	Endocrinology
G9488	Remote e/m est. pt 25mins	Internal Medicine

* Recommended specialty assignment crosswalked; see below.

BILLING CODE 4150–28–C

Comment: Commenters recommended an expected specialty assignment of interventional cardiology for CPT codes 33370, 33894, 33895, 33897, and 33997.

Response: We do not have PE/HR data for the interventional cardiology specialty as it was not part of the PPIS when it was conducted in 2007. We use the cardiology specialty for this specialty's PE/HR data, and therefore, we have crosswalked the CPT codes in question to the cardiology specialty on the list of expected specialty assignments for low volume services.

Comment: Commenters also recommended an expected specialty assignment of hand surgery for CPT code 26705.

Response: During our review of claims data for this code, we found that the most frequently reported specialty for CPT code 26705 was orthopedic surgery, reported more than twice as often as the hand surgery specialty. Therefore, we are finalizing orthopedic surgery and not hand surgery as the expected specialty assignment for CPT code 26705.

We also note for commenters that each HCPCS code that appears on the list of expected specialty assignments for low volume services remains on the list from year to year, even if the volume for the code in question rises to over 100 services for an individual calendar year. The HCPCS codes and expected specialty assignment remain on the list, and will be applied should the volume fall below 100 services in any calendar year; there is no need to ''reactivate'' individual codes as some commenters have suggested in past submissions.

After consideration of the public comments, we are finalizing the updates to the list of expected specialty assignments for low volume services as detailed above.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty specific indirect PE/HR data, calculate specialty specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated

in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS BN. (See ''Specialties excluded from ratesetting calculation'' later in this final rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

- Specialties excluded from ratesetting calculation: For the purposes of calculating the PE and MP RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 2.

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TABLE 2: Specialties Excluded from Ratesetting Calculation

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

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- Crosswalk certain low volume physician specialties: Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- Physical therapy utilization: Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- Identify professional and technical services not identified under the usual TC and 26 modifiers: Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).
- Payment modifiers: Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time

accordingly. Table 3 details the manner in which the modifiers are applied.

TABLE 3: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion
AS	Assistant at Surgery – Physician Assistant	14% (85% * 16%)	Intraoperative portion
50 or LT and RT	Bilateral Surgery	150%	150% of work time
51	Multiple Procedure	50%	Intraoperative portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims	Preoperative + Intraoperative portion
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims	Postoperative portion
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%
CO, CQ	Physical and Occupational Therapy Assistant Services	88%	88%

We also adjust volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

Beginning in CY 2022, section 1834(v)(1) of the Act required that we apply a 15 percent payment reduction for outpatient occupational therapy services and outpatient physical therapy services that are provided, in whole or in part, by a physical therapist assistant (PTA) or occupational therapy assistant (OTA). Section 1834(v)(2)(A) of the Act required CMS to establish modifiers to identify these services, which we did in the CY 2019 PFS final rule (83 FR 59654 through 59661), creating the CQ and CO payment modifiers for services provided in whole or in part by PTAs and OTAs, respectively. These payment modifiers are required to be used on claims for services with dates of service beginning January 1, 2020, as specified in the CY 2020 PFS final rule (84 FR 62702 through 62708). We applied the 15 percent payment reduction to therapy services provided by PTAs (using the CQ modifier) or OTAs (using the CO modifier), as required by statute. Under sections 1834(k) and 1848 of the Act, payment is made for outpatient therapy services at 80 percent of the lesser of the actual charge or applicable fee schedule amount (the allowed charge). The remaining 20 percent is the beneficiary copayment. For therapy services to which the new discount applies, payment will be made at 85 percent of the 80 percent of allowed charges. Therefore, the volume discount factor for therapy services to which the CQ and CO modifiers apply is: (0.20 + (0.80* 0.85), which equals 88 percent.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- *Work RVUs:* The setup file contains the work RVUs from this final rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 (1/((1 + interest rate)^ life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage=1); generally, 150,000 minutes.
usage = variable, see discussion below in this final rule.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, see discussion below in this final rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different

types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than 2 years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS final rule, we finalized a proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For a more detailed discussion of the methodology associated with very short equipment life durations, we refer readers to the CY 2021 PFS final rule (85 FR 84482 through 84483).

- *Maintenance:* We finalized the 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We noted that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.
- *Interest Rate:* In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The Interest rates are listed in Table 4.

TABLE 4: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We did not propose and we are not finalizing any changes to the equipment interest rates for CY 2023.

3. Adjusting RVUs To Match the PE Share of the Medicare Economic Index (MEI)

For CY 2023, as explained in detail in section II.M. of this final rule, we proposed to rebase and revise the Medicare Economic Index (MEI) to reflect more current market conditions faced by physicians in furnishing physicians' services. The MEI is an index that measures changes in the market price of the inputs used to furnish physician services. This index measure is authorized under section 1842(b)(3) of the Act, and is developed by the CMS Office of the Actuary. We believe that the MEI is the best measure available of the relative weights of the three components in payments under the PFS—work, PE and malpractice. Accordingly, we believe that to assure that the PFS payments reflect the relative resources in each of these components as required by section 1848(c)(3) of the Act, the RVUs used in developing rates should reflect the same weights in each component as the MEI. In the past, we have proposed (and subsequently, finalized) to accomplish this by holding the work RVUs constant and adjusting the PE RVUs, the MP RVUs and the CF to produce the appropriate balance in RVUs among the PFS components and payment rates for individual services. The most recent adjustments to the RVUs to reflect changes in the MEI weights were made for the CY 2014 RVUs, when the MEI was last updated. In the CY 2014 PFS proposed rule (78 FR 43287 through 43288) and final rule (78 FR 74236 through 74237), we detailed the steps necessary to accomplish this result (see steps 3, 10, and 18). The CY 2014 proposed and final adjustments were consistent with our longstanding practice to make adjustments to match the RVUs for the PFS components with the MEI cost share weights for the components, including the adjustments described in the CY 1999 PFS final rule (63 FR 58829), CY 2004 PFS final rule (68 FR 63246 and 63247), and CY 2011 PFS final rule (75 FR 73275).

In the past when we have proposed a rebasing and/or revision of the MEI, as we discuss in section II.M. of this final rule, we typically have also proposed to modify steps 3 and 10 to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the rebased and revised MEI cost share weights, as previously described in the CY 2014 PFS final rule (78 FR 74236 and 74237), and to recalibrate the relativity adjustment that we apply in step 18 as described in the CY 2014 PFS final rule. Instead, we proposed to delay the adjustments to the PE pools in steps 3 and 10 and the recalibration of the relativity adjustment in step 18 until the public had an opportunity to comment on the proposed rebased and revised MEI, which is being finalized for CY 2023, as discussed in section II.M. of this final rule. Because we proposed significant methodological and data source changes to the MEI for CY 2023 and significant time has elapsed since

the last rebasing and revision of the MEI, we explained that we believe it is important to allow public comment and finalization of the proposed MEI changes based on the review of public comment before we incorporated the updated MEI into PFS ratesetting, and we believe this is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. We refer readers to the discussion of our comment solicitation in section II.B. of this final rule, where we review our ongoing efforts to update data inputs for PE to aid stability, transparency, efficiency, and data adequacy. Similarly, we delayed the implementation of the proposed rebased and revised MEI for use in the PE geographic practice cost index (GPCI) and solicited comment on appropriate timing for implementation for potential future rulemaking, discussed in detail in section II.G. and section VI. of this final rule.

In light of the proposed delay in using the proposed update to the MEI to make the adjustments to the PE pools in steps 3 and 10 and the relativity adjustment in step 18, we solicited comment on when and how to best incorporate the proposed rebased and revised MEI discussed in section II.M. of the proposed rule into PFS ratesetting, and whether it would be appropriate to consider a transition to full implementation for potential future rulemaking. In section VI. of this final rule, we present the impacts of implementing the proposed rebased and revised MEI in PFS ratesetting through a 4-year transition and through full immediate implementation, that is, with no transition period. Given the significance of the impacts that result from a full implementation and the interaction with other CY 2023 proposals, we did not consider proposing to fully implement a rebased and revised MEI in PFS ratesetting for CY 2023. We solicited comment on other implementation strategies for potential future rulemaking that are not outlined in section VI. of this final rule.

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposed delayed implementation of the rebased and revised MEI in PFS ratesetting until the public had an opportunity to comment on the proposed changes to the MEI, as discussed in section II.M. of this final rule.

Response: We thank the commenters for their support.

Comment: Many commenters expressed concerns with the redistributive impacts discussed in section VI. of the proposed rule, where we discussed the alternative considered to implement the proposed rebased and revised MEI in PFS ratesetting through a 4-year transition for CY 2023. Many of the commenters cited other proposals and their confluence with the proposed rebased and revised MEI as a source of their concerns regarding the implementation of the MEI in PFS ratesetting. Most commenters noted that the AMA has said it intends to collect practice cost data from physician practices in the near future and urged CMS to pause consideration of other sources for the MEI until the AMA's efforts have concluded. A few commenters urged CMS to implement the MEI for PFS ratesetting when appropriate using a 4-year transition to minimize shifts and maintain stability in PFS payments.

Response: We appreciate commenters' feedback, specifically as it relates to updating PFS ratesetting, and will consider this information in future rulemaking. We note that we discuss comments relating to the proposed rebased and revised MEI in section II.M. of this final rule.

4. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2023 direct PE input public use files, which are available on the CMS website under downloads for the CY 2023 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and post service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS'' and ''Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes

with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we continue to believe that in these cases, the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. For additional details, we direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 and 59464).

Following the publication of the CY 2020 PFS proposed rule, one commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of the applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed that it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect that these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. For additional details, we direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584).

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties developing the recommendations. These variations have made it difficult for both the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations will help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database. As we did in previous calendar years, to facilitate rulemaking for CY 2023, we are continuing to display two versions of the Labor Task Detail public use file: one version with the old listing of clinical labor tasks, and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2023 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

b. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. Beginning in CY 2019 and continuing through CY 2022, we conducted a market-based supply and equipment pricing update, using information developed by our contractor, StrategyGen, which updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. Given the potentially significant changes in payment that would occur, in the CY 2019 PFS final rule we finalized a policy to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy, while maintaining stability and allowing interested parties the opportunity to address potential concerns about changes in payment for particular items. This 4-year transition period to update supply and equipment pricing concluded in CY 2022; for a more detailed discussion, we refer readers to the CY 2019 PFS final rule with comment period (83 FR 59473 through 59480).

For CY 2023, we proposed to update the price of eight supplies and two equipment items in response to the public submission of invoices following the publication of the CY 2022 PFS final rule. The eight supply and equipment items with proposed updated prices are listed in the valuation of specific codes section of the preamble under Table 19, CY 2023 Invoices Received for Existing Direct PE Inputs.

We received the following comments on our proposal to update the price of eight supplies and two equipment items in response to the public submission of invoices following the publication of the CY 2022 PFS final rule:

Comment: Several commenters submitted comments to clarify that the invoice they included in their submission that was identified as the Lysing Reagent (SL089) supply was intended for a different supply item, the Lysing Solution (SL039). The commenters stated that our proposed reduction of the price for the SL089 supply appeared to be based on the invoice they had as misidentified as being for the SL089 supply, when it was intended for the SL039 supply. The commenters asked CMS to disregard the earlier mistaken submission and submitted additional invoices with updated pricing for the SL089 supply for consideration to correct the oversight in their original submission.

Response: We appreciate the clarification from the commenters and the updated invoices with pricing information for the SL089 supply. We are finalizing an increase in the price of the Lysing Reagent (SL089) supply to $5.53 based on the average of the ten submitted invoices from the commenter. (Note: the separate discussion of the SL039 supply below is based on a different invoice submitted by a different interested party unconnected to the SL089 supply. We believe it is appropriate to consider and revise the price for the SL089 supply based on the clarification and new invoices submitted by commenters for that supply. However, given that the invoice for SL039 submitted by these commenters was not intended to be submitted for the SL039 supply, we did not consider the invoice for SL039 that was mistakenly submitted by these commenters.)

Comment: Several commenters stated their support for the proposed pricing changes to the EP014 and EP088 equipment items and the SA117, SK082, SL024, SL030, SL061, and SL469 supply items. The commenters urged CMS to finalize them as proposed in the final rule.

Response: We appreciate the support for our proposed pricing from the commenters.

In the proposed rule, we did not propose to update the price of another eight supplies and two equipment items which were the subject of public submission of invoices. Our rationale for not updating these prices is detailed below:

- *Acetic acid 5% (SH001):* We received an invoice submission that would suggest an increase in price from 3 cents per ml to 9.5 cents per ml for the SH001 supply. However, the invoice stated that this price was for an ''Alcian Blue 1% in 3% Acetic Acid pH 2.5'' supply and it is not clear that this represents the same supply as the ''Acetic acid 5%'' described by the SH001 supply item. We also do not believe that the typical price for this supply has increased 200 percent in the 3 years since StrategyGen researched its pricing, especially given that we increased the price for the SH001 supply from 1.2 cents in CY 2019 to its current price of 3 cents for CY 2022.
- *Cytology, lysing soln (CytoLyt) (SL039):* We received an invoice submission that would suggest an increase in price from 6 cents per ml to 80 cents per ml for the SL039 supply. We do not believe that the typical price for this supply has increased 1200% in the 3 years since StrategyGen researched its pricing, especially given that we increased the price for the SL039 supply from 3.4 cents in CY 2019 to its current price of 6 cents for CY 2022.
- *Fixative (for tissue specimen) (SL068):* We received an invoice submission that would suggest an increase in price from 1.3 cents per ml to $4.87 for the SL068 supply. We believe that this was the result of confusion on the part of the interested party regarding the unit quantity for the SL068 supply. This item is paid on a per ml basis and not a per unit basis; there was not enough information on the submitted invoice to determine the price for the SL068 supply on a per ml basis.
- *Ethanol, 100% (SL189):* We received an invoice submission that would suggest an increase in price from 0.33 cents per ml to 1.2 cents per ml for the SL189 supply. However, we noted that the invoice was based on the price for a single gallon of 100% ethanol which is typically sold in much larger quantities than a single gallon. We found that 100% ethanol was readily available for sale online in larger unit sizes and the current price of 0.33 cents per ml (based on the past StrategyGen market research) appears to be accurate based on online bulk pricing. We also found that the submitted invoices for the ethanol, 70% (SL190), ethanol, 95% (SL248), and stain, PAP OG–6 (SL491) supplies were also based on pricing for a single gallon. Each of these supply items was also available for purchase in larger unit quantities which indicated that the current pricing remained typical for these supplies. Therefore, we did not propose to update the prices for the SL189, SL190, SL248 or SL491 supply, as we do not believe that the higher prices paid for smaller quantities of these supplies would be typical.
- *Biohazard specimen transport bag (SM008):* We received an invoice submission that would suggest an increase in price from 8 cents to 45 cents for the SM008 supply. However, it is not clear that the item described on the invoice is the same item as the SM008 supply. The invoice states only that the price is for ''Supplied Case Red Bags'' which was not enough information to determine if this would be typical for the SM008 supply. We also do not believe that the typical price for this supply has increased 460 percent in the 3 years since StrategyGen researched its pricing, especially given that we increased the price for the SM008 supply from 3.5 cents in CY 2019 to its current price of 8 cents for CY 2022.
- *International Normalized Ratio (INR) analysis and reporting system w-software (EQ312):* We did not receive an invoice for this equipment item, only a letter stating that the cost of the EQ312 equipment should be increased from the current price of $19,325 to $1,600,000. We previously finalized a policy in the CY 2011 PFS final rule (75 FR 73205) to update supply and equipment prices through an invoice submission process. We require pricing data indicative of the typical market price of the supply or equipment item in question to update the price. It is not sufficient to state a different price without providing information to support a change in pricing. Since we did not receive an invoice to support the higher costs asserted in the letter, we did not propose a new price for the EQ312 equipment item. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*. We also noted that in order to be considered a direct PE input, an equipment item must be individually allocable to a particular patient for a particular service. Costs associated with the implementation, maintenance, and upgrade of equipment that is not individually allocable to a particular patient for a particular service, or other costs associated with running a practice, would typically be classified as forms of indirect PE under our methodology.

Prior to the publication of the proposed rule, the same interested parties that addressed the pricing of the EQ312 equipment item questioned the assignment of the General Practice specialty crosswalk for indirect PE for home Prothrombin Time (PT)/INR monitoring services. These individuals stated that the predominant code used for PT/INR monitoring (HCPCS code G0249) will be significantly and negatively impacted by the continuing implementation over a 4-year period of changes in the clinical labor rates

finalized in the CY 2022 PFS final rule (86 FR 65024). The individuals requested that CMS change the crosswalk for home PT/INR monitoring services to All Physicians or Pathology which would partially offset the reduction that HCPCS code G0249 is facing due to changes in the clinical labor rates.

We noted for these interested parties in the CY 2021 PFS final rule (85 FR 84477 and 84478)that we finalized a crosswalk to the General Practice specialty for home PT/INR monitoring services (HCPCS codes G0248, G0249, and G0250). The data submitted by the commenters at the time indicated that the direct-to-indirect cost percentages to furnish home PT/INR monitoring are in the range of 31:69, similar to the ratio associated with the General Practice specialty. We disagreed, as we did in response to comments in the CY 2021 PFS final rule, that these home PT/INR monitoring services should be reassigned to a different specialty that is less reflective of the cost structure for these services to offset reductions in payment for the services that result from an unrelated policy proposal (the clinical labor pricing update). We also noted that we had not received any new information about PT/INR monitoring services since CY 2021 to indicate that Pathology would be more accurate choices for use in indirect PE allocation but are open to receiving new relevant information that CMS could consider in future rulemaking. As such, we did not propose to change the assigned specialty for PT/INR services; we direct interested parties to the previous discussion of this topic in the CY 2021 PFS final rule (85 FR 84477 and 84478) and again in the CY 2022 PFS final rule (86 FR 65000). Interested parties are encouraged to submit new information to support the most accurate specialty choice to use in indirect PE allocation for PT/INR monitoring services distinct from what has previously been reviewed during the last two rule cycles.

Comment: A commenter submitted additional direct and indirect cost data associated with pricing the INR analysis and reporting system w-software (EQ312) equipment. The commenter stated that they arrived at this amount based upon detailed review of all of the software system and related expenses involved with furnishing home INR monitoring services, including up front equipment and software purchases that comprise direct equipment practice expenses, up front maintenance and support services that comprise indirect practice expenses, and recurring support and telecommunications services that also comprise indirect practice expenses. The commenter submitted invoices detailing a one-time direct cost of $69,621, a one-time indirect cost of $84,126.31, and recurring annual costs of $963,638.52 associated with the EQ312 equipment.

Response: We agree with the commenter that the invoices support an increase in the purchase price of the equipment from the current $19,325 to the price of $69,621 listed on the invoices. However, we disagree that the one-time indirect cost of $84,126.31 or recurring annual costs of $963,638.52 listed on the invoices would constitute forms of direct PE which would be included in the equipment's price. The indirect costs on the submitted invoices are for project management and service order costs while the recurring annual costs comprise monthly maintenance and telecommunications expenses. We agree that these are real costs associated with the software, however they are classified as forms of indirect PE under our current methodology. The equipment cost formula that we use already incorporates maintenance and interest rates costs into the per-minute pricing calculation; if we were to include these expenses in the equipment cost as a form of direct PE, we would be making duplicative payment for the same expenses. We are therefore finalizing an increase in the price of the EQ312 equipment to $69,621 but not including the indirect and recurring annual costs in the equipment price as they are classified as forms of indirect PE.

Comment: The same commenter reiterated their previous request made in PFS rulemaking for CY 2021 for CMS to change the crosswalk for home PT/INR monitoring services from the previously finalized General Practice specialty to the All Physicians or Pathology specialty. The commenter stated that the code used to report ongoing home PT/INR monitoring (HCPCS code G0249) will again be significantly and negatively impacted in CY 2023 as a result of changes in the clinical labor rates with the corresponding budget neutrality adjustment and the drop in the conversion factor. The commenter stated that the Pathology specialty provides a better reflection of the indirect to direct costs associated with home PT/INR monitoring and also reflects a more appropriate indirect practice cost index (IPCI) for a service with very high indirect costs, such as home PT/IN monitoring. The commenter stated their belief that the indirect cost data captured in their submitted invoices supports a crosswalk to the Pathology specialty given the higher indirect costs of furnishing these services, including the on-going software costs that are not captured in the direct PE input; and that this specialty crosswalk change would help offset the cuts in the proposed rate for HCPCS code G0249.

Response: We continue to believe that assignment of the Pathology specialty for home PT/INR monitoring services as requested by the commenters would not be appropriate. As we stated in the proposed rule, we continue to disagree that these home PT/INR monitoring services should be reassigned to a different specialty that is less reflective of the cost structure for these services to offset reductions in payment that result from an unrelated policy proposal (the clinical labor pricing update). The commenter stated that home PT/INR monitoring services have high indirect expenses and suggested that this supported assignment of a specialty with a higher direct-to-indirect expense ratio than General Practice (which has a 31 to 69 percent ratio), such as Pathology (which has a 26 to 74 percent ratio). However, this is a misunderstanding of the direct-to-indirect ratio for each specialty, which is a ratio based on data from the Physician Practice Expense Information Survey (PPIS) conducted back in 2007. The direct-to-indirect ratio is merely a ratio, and not indicative of a specialty having higher or lower indirect expenses in absolute terms. Higher indirect expenses for a specialty are not correlated with a higher percentage of indirects as compared with directs in that ratio; in fact, the Independent Diagnostic Testing Facility specialty has both the highest indirect expenses of any specialty, as well as a low direct to indirect ratio (50 to 50%) precisely because IDTFs also have very high direct expenses as well. Similarly, the Pathology specialty had lower indirect expenses on the PPIS than the General Practice specialty; this contradicts the commenter's contention that the high indirect costs for home PT/INR monitoring services would justify a change to the Pathology specialty. We continue to believe that the data submitted by the commenters in the CY 2021 PFS final rule (85 FR 84477 and 84478) indicated that the direct-to-indirect cost percentages to furnish home PT/INR monitoring are not reflective of the Pathology specialty.

We note that the PE methodology, which relies on the allocation of indirect costs based on the magnitude of direct costs, should appropriately reflect the typical costs for the specialty the commenters suggest. However, we are cognizant that approach may not work

in all cases, particularly for newer services with costs that are not well accounted for in our PE methodology, or services with cost structures that do not necessarily reflect the specialties furnishing them. Although we have previously assigned the General Practice specialty to these codes, interested parties have provided additional information about these services suggesting assignment to a different specialty for purposes of allocating indirect cost. We believe that, as we work to identify ways to update the PE methodology and our data sources to better reflect costs for all services and changes in medical practice, it is best to apply a consistent approach in setting rates that does not over-allocate cost, which could result in significant increases in payments for these services. Considering our concerns, we will switch the specialty assignment for these services to the All Physician specialty, consistent with how we have treated other new services that do not quite fit our PE methodology in recent rulemaking (see for example the discussion of HCPCS codes G2082 and G2083 in the CY 2022 PFS final rule (86 FR 65014 and 65015) and again in this rule). We believe this will allow for improved stability in payments, and preserve access to this care for beneficiaries, while we work to identify longer term solutions.

- *Remote musculoskeletal therapy system (EQ402):* We received an invoice submission for a price of $1,000 for the EQ402 equipment item. Since this equipment already has a price of $1,000 we did not propose to make any changes in the pricing; we thank the interested party for their invoice submission confirming the current price.

The following are additional comments that we received associated with supply and equipment pricing:

Comment: Several commenters requested the creation of a new supply code to describe an alternate form of a basic injection pack. Commenters stated that for many services the use of Chloraprep (chlorhexidine) for intact skin preparation has become more typical than Betadine (povidone-iodine solution) and that the current basic injection pack described by supply code SA041 no longer accurately reflects typical resource use. Commenters requested that CMS create an alternative pack which instead includes Chloraprep (chlorhexidine) so that specialties can select the injection pack with the most appropriate antiseptic. Commenters requested that the new pack should mirror the SA041 basic injection pack with the addition of the patient prep swab, 1.5 ml chloraprep (SJ081) supply and removal of the Betadine povidone soln (SJ041) and sponge tipped applicator (SG009) supplies.

Response: We appreciate the feedback from the commenters on the changing nature of what supplies are typically included in basic injection packs, and as a result, we are creating an alternate injection pack with the new supply code SA135 which will be priced at $14.12 as detailed in Table 5.

TABLE 5: Alternate Injection Pack Supplies (SA135)

SA135	Pack, alternate injection	Number	Pack	14.116
	bandage, strip 0.75in x 3in	1	item	0.410
	underpad 2ftx3ft (Chux)	1	item	0.320
	gauze, sterile 4in x 4in	2	item	0.190
	gloves, sterile	2	pair	0.910
	gown, staff, impervious	1	item	1.186
	mask, surgical	1	item	0.430
	drape, sterile, for Mayo stand	1	item	1.070
	needle, 18-27g	2	item	0.040
	drape, sterile barrier 16in x 29in	1	item	0.510
	gown, surgical, sterile	1	item	5.130
	cap, surgical	1	item	1.140
	syringe 3ml	1	item	0.250
	lidocaine 1%-2% inj (Xylocaine)	5	ml	0.060
Added	**swab, patient prep, 1.5 ml (chloraprep)**	**1**	**item**	**1.090**

After consideration of the public comments, we are finalizing the creation of the SA135 alternate injection pack. We note that this supply is not currently included in any CPT or HCPCS codes but has been added to our direct PE database for future use in services.

Comment: A commenter expressed concern that the prices for the injectable fluorescein (SH033) and lidocaine (SH049) supplies were too low. The commenter submitted invoices for both supply items and requested that they be used to update their respective prices.

Response: After reviewing the invoices, we are updating the price of the fluorescein injectable (5ml uou) (SH033) supply from $38.02 to $49.13 based on an average of prices from five submitted invoices. We did not include the sixth invoice for the SH033 supply (with a listed price of $64.80) in this average as it described a different type of injectable fluorescein from the other five invoices (it described 2 mL of a 25% solution as opposed to 5 mL of a 10% solution on the other five invoices).

We are not updating the price of the lidocaine 2% w-epidural injectable (Xylocaine w-epi) (SH049) supply as the two submitted invoices were not usable for pricing. One of the invoices detailed a 3.5% type of lidocaine while the SH049 supply code specifies that it is for 2% lidocaine. The other submitted invoice specifically noted that it was a ''preservative free'' version of lidocaine which was more expensive than the typical item; we do not agree that this invoice would be accurate for establishing a new national price for the SH049 supply. We remain interested in additional information regarding updated pricing information for the SH049 and other supply/equipment codes; as noted below, interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking

process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

We did not make any proposals associated with HCPCS codes G0460 (*Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment*) or G0465 (*Autologous platelet rich plasma (prp) for diabetic chronic wounds/ulcers, using an FDA-cleared device (includes administration, dressings, phlebotomy, centrifugation, and all other preparatory procedures, per treatment)*) in the CY 2023 PFS proposed rule. In the CY 2021 PFS final rule, we established contractor pricing for HCPCS code G0460 for CY 2021 (85 FR84497–84498). In the CY 2022 PFS final rule, we finalized a policy to maintain contractor pricing for HCPCS code G0460 as we did not have sufficient information to establish national pricing, and we did not receive public comments on either the proposal or comment solicitation to support establishing a national payment rate (86 FR 65019–65020). It remains unclear to us what the typical supply inputs would be for HCPCS code G0460 and whether they would include the use of the new 3C patch system.

Comment: Following the publication of the CY 2023 PFS proposed rule, we received two comments on the pricing of HCPCS codes G0460 and G0465, and the 3C patch system supply which is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and mechanically or surgically-debrided wounds. One commenter submitted invoices associated with the pricing of the 3C patch system (SD343) supply for which we established a price of $625.00 in the CY 2021 PFS final rule (85 FR 84498). The commenter requested that CMS update its supply database based on invoices submitted for SD343 to reflect an updated price of $750.00 per unit. The commenter also requested national pricing for HCPCS codes G0460 and G0465, expressing concern that insufficient payment disproportionately impacts vulnerable populations. The commenter requested a payment rate of $1,408.90 for HCPCS G0465 in the office setting, stating that this rate would appropriately account for the purchase of the 3C patch, as well as the other related costs and supply inputs required for point of care creation and administration.

Another commenter requested the establishment of new codes to allow for quantity-specific payment when multiple patches are needed to treat wounds of various surface sizes. Both commenters stated that many months have passed since CMS updated NCD 270.3 in April 2021 (for Blood-Derived Products for Chronic, Non-Healing Wounds), however, the 3C patch remains nearly inaccessible in the office and facility settings because of insufficient payment by MACs. Both commenters suggested that, to date, just one MAC has assigned a payment rate for HCPCS code G0465, which the commenters believe is too low to cover the cost to purchase and administer the patch. One commenter expressed support for the professional fee to administer the patch in the facility setting determined by this MAC, First Coast ($135.97), with the appropriate geographic adjustments, and urged CMS either to apply this rate nationally or to require MACs to set a carrier price in a timely and transparent manner. Both commenters stated that health care providers in the remaining MAC jurisdictions have faced denials even when they follow the coverage guidelines specified by our NCD 270.3. One commenter contended that, as of 2019, 27.5 percent of the traditional Medicare beneficiaries had a diabetes diagnosis. Both commenters highlighted that, within this population, the prevalence of diabetes is significantly higher among Medicare FFS beneficiaries who identify as Native American or Black/African American relative to their white counterparts, and furthermore, these historically underserved populations are also more likely to develop foot ulcers and infections that require amputation. The commenters stated that the 3C Patch has the potential to help cure these concerning health disparities and requested that we make the 3C Patch accessible by establishing national pricing for HCPCS codes G0460 and G0465.

Response: We do not have enough information to establish national pricing at this time. We will consider the commenters' feedback for future rulemaking while maintaining contractor pricing for CY 2023, which will allow for more flexibility for contractors to establish appropriate pricing using available information. We appreciate the invoice submission with additional pricing information for the SD343 supply and will update our supply database for supply code SD343 at a price of $678.57 based on an average of the submitted invoices.

(1) Invoice Submission

We remind readers that we routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

c. Clinical Labor Pricing Update

Section 220(a) of the PAMA provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

Beginning in CY 2019, we updated the supply and equipment prices used for PE as part of a market-based pricing transition; CY 2022 was the final year of this 4-year transition. We initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the supply and equipment pricing for CY 2019, and we finalized a policy in CY 2019 to phase in the new pricing over a period of 4 years. However, we did not propose to update the clinical labor pricing, and the pricing for clinical labor has remained unchanged during this pricing transition. Clinical labor rates were last updated for CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available; we refer readers to the full discussion in the CY 2002 PFS final rule for additional details (66 FR 55257 through 55262).

Interested parties raised concerns that the long delay since clinical labor

pricing was last updated created a significant disparity between CMS' clinical wage data and the market average for clinical labor. In recent years, a number of interested parties suggested that certain wage rates were inadequate because they did not reflect current labor rate information. Some interested parties also stated that updating the supply and equipment pricing without updating the clinical labor pricing could create distortions in the allocation of direct PE. They argued that since the pool of aggregated direct PE inputs is budget neutral, if these rates are not routinely updated, clinical labor may become undervalued over time relative to equipment and supplies, especially since the supply and equipment prices are in the process of being updated. There was considerable interest among interested parties in updating the clinical labor rates, and when we solicited comment on this topic in past rules, such as in the CY 2019 PFS final rule (83 FR 59480), interested parties supported the idea.

Therefore, we proposed to update the clinical labor pricing for CY 2022, in conjunction with the final year of the supply and equipment pricing update (86 FR 39118 through 39123). We believed it was important to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates. We proposed to use the methodology outlined in the CY 2002 PFS final rule (66 FR 55257), which draws primarily from BLS wage data, to calculate updated clinical labor pricing. As we stated in the CY 2002 PFS final rule, the BLS' reputation for publishing valid estimates that are nationally representative led to the choice to use the BLS data as the main source. We believe that the BLS wage data continues to be the most accurate source to use as a basis for clinical labor pricing and this data will appropriately reflect changes in clinical labor resource inputs for purposes of setting PE RVUs under the PFS. We used the most current BLS survey data (2019) as the main source of wage data for our CY 2022 clinical labor proposal.

We recognized that the BLS survey of wage data does not cover all the staff types contained in our direct PE database. Therefore, we crosswalked or extrapolated the wages for several staff types using supplementary data sources for verification whenever possible. In situations where the price wages of clinical labor types were not referenced in the BLS data, we used the national salary data from the Salary Expert, an online project of the Economic Research Institute that surveys national and local salary ranges and averages for thousands of job titles using mainly government sources. (A detailed explanation of the methodology used by Salary Expert to estimate specific job salaries can be found at *www.salaryexpert.com*). We previously used Salary Expert information as the primary backup source of wage data during the last update of clinical labor pricing in CY 2002. If we did not have direct BLS wage data available for a clinical labor type, we used the wage data from Salary Expert as a reference for pricing, then crosswalked these clinical labor types to a proxy BLS labor category rate that most closely matched the reference wage data, similar to the crosswalks used in our PE/HR allocation. For example, there is no direct BLS wage data for the Mammography Technologist (L043) clinical labor type; we used the wage data from Salary Expert as a reference and identified the BLS wage data for Respiratory Therapists as the best proxy category. We calculated rates for the ''blend'' clinical labor categories by combining the rates for each labor type in the blend and then dividing by the total number of labor types in the blend.

As in the CY 2002 clinical labor pricing update, the proposed cost per minute for each clinical staff type was derived by dividing the average hourly wage rate by 60 to arrive at the per minute cost. In cases where an hourly wage rate was not available for a clinical staff type, the proposed cost per minute for the clinical staff type was derived by dividing the annual salary (converted to 2021 dollars using the Medicare Economic Index) by 2080 (the number of hours in a typical work year) to arrive at the hourly wage rate and then again by 60 to arrive at the per minute cost. We ultimately finalized the use of median BLS wage data, as opposed to mean BLS wage data, in response to comments in the CY 2022 PFS final rule. To account for the employers' cost of providing fringe benefits, such as sick leave, we finalized the use of a benefits multiplier of 1.296 based on a BLS release from June 17, 2021 (USDL–21–1094). As an example of this process, for the Physical Therapy Aide (L023A) clinical labor type, the BLS data reflected a median hourly wage rate of $12.98, which we multiplied by the 1.296 benefits modifier and then divided by 60 minutes to arrive at the finalized per-minute rate of $0.28.

After considering the comments on our CY 2022 proposals, we agreed with commenters that the use of a multi-year transition would help smooth out the changes in payment resulting from the clinical labor pricing update, avoiding potentially disruptive changes in payment for affected interested parties, and promoting payment stability from year-to-year. We believed it would be appropriate to use a 4-year transition, as we have for several other broad-based updates or methodological changes. While we recognized that using a 4-year transition to implement the update means that we will continue to rely in part on outdated data for clinical labor pricing until the change is fully completed in CY 2025, we agreed with the commenters that these significant updates to PE valuation should be implemented in the same way, and for the same reasons, as for other major updates to pricing such as the recent supply and equipment update. Therefore, we finalized the implementation of the clinical labor pricing update over 4 years to transition from current prices to the final updated prices in CY 2025. We finalized the implementation of this pricing transition over 4 years, such that one quarter of the difference between the current price and the fully phased-in price is implemented for CY 2022, one third of the difference between the CY 2022 price and the final price is implemented for CY 2023, and one half of the difference between the CY 2023 price and the final price is implemented for CY 2024, with the new direct PE prices fully implemented for CY 2025. An example of the transition from the current to the fully-implemented new pricing that we finalized in the CY 2022 PFS final rule is provided in Table 6.

TABLE 6: Example of Clinical Labor Pricing Transition

Current Price	$1.00	
Final Price	$2.00	
Year 1 (CY 2022) Price	$1.25	1/4 difference between $1.00 and $2.00
Year 2 (CY 2023) Price	$1.50	1/3 difference between $1.25 and $2.00
Year 3 (CY 2024) Price	$1.75	1/2 difference between $1.50 and $2.00
Final (CY 2025) Price	$2.00	

(1) CY 2023 Clinical Labor Pricing Update Proposals

For CY 2023, we received information from one interested party regarding the pricing of the Histotechnologist (L037B) clinical labor type. The interested party provided data from the 2019 Wage Survey of Medical Laboratories which supported an increase in the per-minute rate from the $0.55 finalized in the CY 2022 PFS final rule to $0.64. This rate of $0.64 for the L037B clinical labor type is a close match to the online salary data that we had for the Histotechnologist and matches the $0.64 rate that we initially proposed for L037B in the CY 2022 PFS proposed rule. Based on the wage data provided by the commenter, we proposed this $0.64 rate for the L037B clinical labor type for CY 2023; we also proposed a slight increase in the pricing for the Lab Tech/Histotechnologist (L035A) clinical labor type from $0.55 to $0.60 as it is a blend of the wage rate for the Lab Technician (L033A) and Histotechnologist clinical labor types. We also proposed the same increase to $0.60 for the Angio Technician (L041A) clinical labor type, as we previously established a policy in the CY 2022 PFS final rule that the pricing for the L041A clinical labor type would match the rate for the L035A clinical labor type (86 FR 65032). The proposed pricing increase for these three clinical labor types is included in Table 7; the CY 2023 pricing for all other clinical labor types would remain unchanged from the pricing finalized in the CY 2022 PFS final rule.

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TABLE 7: Proposed CY 2023 Clinical Labor Pricing

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y2 Phase-In Rate Per Minute	Total % Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	0.255	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	0.310	38%
L030A	Lab Tech/MTA	L033A, L026A	0.30	0.46	0.380	53%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	0.380	38%
L033A	Lab Technician	BLS 29-2010	0.33	0.55	0.440	67%
L033B	Optician/COMT	BLS 29-2081, BLS 29-2057	0.33	0.39	0.360	18%
L035A*	Lab Tech/Histotechnologist	L033A, L037B	0.35	0.60	0.473	70%
L037A	Electrodiagnostic Technologist	BLS 29-2098	0.37	0.44	0.405	19%
L037B*	Histotechnologist	BLS 29-2010	0.37	0.64	0.505	73%
L037C	Orthoptist	BLS 29-1141	0.37	0.76	0.565	105%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	0.455	46%
L037E	Child Life Specialist	BLS 21-1021	0.37	0.49	0.430	32%
L038A	COMT/COT/RN/CST	BLS 29-2057, BLS 29-2055, L051A, BLS 19-4010	0.38	0.52	0.450	37%
L038B	Cardiovascular Technician	BLS 29-2031	0.38	0.60	0.490	58%
L038C	Medical Photographer	BLS 29-2050	0.38	0.38	0.383	0%
L039A	Certified Retinal Angiographer	BLS 29-9000	0.39	0.52	0.455	33%
L039B	Physical Therapy Assistant	BLS 31-2021	0.39	0.61	0.500	56%
L039C	Psychometrist	BLS 21-1029	0.39	0.64	0.517	62%
L041A*	Angio Technician	L035A	0.41	0.60	0.503	45%
L041B	Radiologic Technologist	BLS 29-2034	0.41	0.63	0.520	54%
L041C	Second Radiologic Technologist for Vertebroplasty	BLS 29-2034	0.41	0.63	0.520	54%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	0.525	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	0.530	52%
L043A	Mammography Technologist	BLS 29-2034	0.43	0.63	0.530	47%
L045A	Cytotechnologist	BLS 29-2035	0.45	0.76	0.605	69%
L045B	Electron Microscopy Technologist	BLS 29-1124	0.45	0.89	0.670	98%
L045C	CORF social worker/psychologist	BLS 21-1022, BLS 19-3031	0.45	0.70	0.575	56%
L046A	CT Technologist	BLS 29-2035	0.46	0.76	0.610	65%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	0.615	62%
L047B	REEGT (Electroencephalographic Tech)	BLS 29-2035	0.47	0.76	0.615	62%
L047C	RN/Respiratory Therapist	L051A, L042B	0.47	0.70	0.585	49%
L047D	RN/Registered Dietician	L051A, BLS 29-1031	0.47	0.70	0.585	49%
L049A	Nuclear Medicine Technologist	BLS 29-2033	0.62	0.81	0.713	32%
L050A	Cardiac Sonographer	BLS 29-2032	0.50	0.77	0.635	54%
L050B	Diagnostic Medical Sonographer	BLS 29-2032	0.50	0.77	0.635	54%
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	0.695	78%
L050D	Second Radiation Therapist for IMRT	BLS 29-1124	0.50	0.89	0.695	78%
L051A	RN	BLS 29-1141	0.51	0.76	0.635	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	0.640	51%
L051C	RN/CORF	L051A	0.51	0.76	0.635	49%
L052A	Audiologist	BLS 29-1181	0.52	0.81	0.665	56%
L053A	RN/Speech Pathologist	L051A, L055A	0.53	0.79	0.660	49%
L054A	Vascular Technologist	BLS 19-1040	0.54	0.91	0.725	69%
L055A	Speech Pathologist	BLS 29-1127	0.55	0.82	0.685	49%
L056A	RN/OCN	BLS 29-2033	0.79	0.81	0.800	3%
L057A	Genetics Counselor	BLS 29-9092	0.57	0.85	0.709	50%
L057B	Behavioral Health Care Manager	BLS 21-1018	0.57	0.57	0.570	0%
L063A	Medical Dosimetrist	BLS 19-1040	0.63	0.91	0.770	44%

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y2 Phase-In Rate Per Minute	Total % Change
L107A	Medical Dosimetrist/Medical Physicist	L063A, L152A	1.08	1.52	1.298	41%
L152A	Medical Physicist	AAPM Data	1.52	2.14	1.832	41%

* Updated for CY 2023

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Comment: Several commenters noted that there was an error in the proposed clinical labor pricing table in the CY 2023 PFS proposed rule (87 FR 45874) where the final rate per minute for the L041A Angio Technician clinical labor type was incorrectly listed at 0.58 rather than the correct 0.60 as specified in the preamble text.

Response: We agree that the incorrect rate per minute for the L041A clinical labor type was reflected in Table 5 of the proposed rule, and have corrected this error in Table 7 of this final rule. We apologize for any confusion that may have been caused by this mistake.

As was the case for the market-based supply and equipment pricing update, the clinical labor rates will remain open for public comment over the course of the 4-year transition period. We updated the pricing of a number of clinical labor types in the CY 2022 PFS final rule in response to information provided by commenters. For the full discussion of the clinical labor pricing update, we direct readers to the CY 2022 PFS final rule (86 FR 65020 through 65037).

The following is a summary of the comments we received and our responses.

Comment: Several commenters stated their support for the proposed pricing updates to the Histotechnologist (L037B) and the Lab Tech/Histotechnologist (L035A) clinical labor types and urged CMS to finalize the updated pricing.

Response: We appreciate the support for our proposals from the commenters.

Comment: Several commenters requested that CMS update the clinical labor description of the Angio Technician (L041A) clinical labor type to ''Vascular Interventional Technologist.'' The commenters stated that this updated title for the L041A clinical labor type would better align with industry recognition of the advanced certification required to assist physicians with minimally invasive, image-guided vascular procedures.

Response: We appreciate the feedback and are finalizing a change in the descriptive text of the L041A clinical labor type from ''Angio Technician'' to ''Vascular Interventional Technologist'' as requested by the commenter.

Comment: Several commenters disagreed with the proposed pricing for several different technologist clinical labor types. The commenters stated that basic certification is required for a radiologic technologist and that there are additional advanced modality certifications, such as for Computed Tomography (CT), Magnetic Resonance (MR), and Vascular Intervention (VI), which require additional educational programs and training for these advanced modalities/disciplines. The commenters stated that the proposed pricing for the Vascular Interventional Technologist (L041A), the Mammography Technologist (L043A), the CT Technologist (L046A), and the MRI Technologist (L047A) clinical labor types did not reflect the training and certification required for these occupations. The commenters submitted wage data from the 2022 Radiologic Technologist Wage and Salary Survey and requested that the pricing for these four clinical labor types be updated to reflect the wage data from the submitted survey.

Response: When we initiated the clinical labor pricing update last year, we lacked specific wage data for the Vascular Interventional Technologist (L041A), the Mammography Technologist (L043A), and the CT Technologist (L046A) clinical labor types; and relied on crosswalks for their pricing. Based on the information contained in the 2022 Radiologic Technologist Wage and Salary Survey, we now have specific wage data which will allow us to no longer rely on crosswalks for pricing for these clinical labor types. Therefore, we are finalizing an update in the pricing of these three clinical labor types: from 0.60 to 0.84 for the Vascular Interventional Technologist (L041A), from 0.63 to 0.79 for the Mammography Technologist (L043A), and from 0.76 to 0.78 for the CT Technologist (L046A). For the MRI Technologist (L047A), we were able to make use of direct BLS wage data for the occupation. In addition, since we continue to believe that the BLS is the most accurate source of information for wage data, we are not finalizing an increase in the pricing of the L047A clinical labor type. As a reminder, CY 2023 is the second year of the four-year transition to the updated clinical labor pricing, and we will continue to transition the prices established for these three clinical labor types over the next two years of the update.

Comment: A commenter thanked CMS for the agency's recent work in updating clinical labor pricing and stated that nurses and other nonphysician providers have been drastically undervalued for many years which could help to alleviate staffing shortages. The commenter stated that the table of clinical labor types in the proposed rule listed registered nurses (RNs) as their own category for labor pricing under the L051A clinical labor code, but then also included RNs in eight other categories of clinical labor with other practitioners. The commenter requested having RNs identified uniquely and removing the RN option from the other clinical labor categories, as the commenter stated that leaving RNs in other categories would only make the clinical labor update more confusing and could end up disadvantaging RNs in the long term which could exacerbate the current staffing shortage and worsen patient care.

Response: We do not agree that RNs should be removed from the other eight clinical labor types currently listed in our direct PE database. There is a long history of using these ''blended'' clinical labor categories under the PFS, and together these eight clinical labor types make up the overwhelming majority of all clinical labor (especially the RN/LPN/MTA blend described by the L037D clinical labor code). In the absence of alternative pricing information to value these blended clinical labor types, we continue to believe that the proposed prices are the most accurate valuations. We also note for the commenter that the pricing for the RN (L051A) clinical labor type is drawn directly from BLS wage data and the inclusion of RNs in other ''blended'' clinical labor types has no effect on the pricing of the L051A category itself.

Comment: A commenter stated that the current RN/LPN (L042A) clinical labor type assigned to CPT code 36516 did not accurately reflect the costs associated with this procedure. The

commenter stated that CPT code 36516 is a complex extracorporeal blood therapy procedure, conducted over a 5–1/2 to 6-hour period, that requires extensively trained and experienced nurse operators known as apheresis nurses. The commenter stated that the current assignment of the RN/LPN (L042A) clinical labor type for CPT code 36516 seriously undervalues the critical nurse labor cost component of this nearly six-hour procedure and requested that CMS establish a new ''Apheresis Nurse'' clinical labor type with a valuation of approximately $1.14 per minute. The commenter also stated that there are additional supply items not currently captured in the direct PE inputs for CPT code 36516 including a 4-liter accessory waste bag, several types of fluids, and biohazard waste costs.

Response: We remind the commenter that we did not propose the creation of any new clinical labor types nor did we propose any changes in the direct PE inputs for CPT code 36516. If the commenter has reason to believe that the RN/LPN (L042A) clinical labor type is not capturing the typical labor costs associated with CPT code 36516 or that there are additional supply costs not being captured in its direct PE inputs, we encourage them to nominate CPT code 35616 as potentially misvalued for additional review.

Comment: Several commenters stated that, to promote predictability and stability in physician payments and mitigate the financial impacts of significant fluctuations in physician payments that might accompany the clinical labor pricing update, CMS should consider using a threshold to limit the level of reductions in payments for specific services that would occur in a single year. Several commenters noted that in the CY 2023 Inpatient Prospective Payment System final rule, CMS implemented a permanent 5 percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year; the commenters suggested applying a similar cap of 5 percent, 10 percent, or 15 percent for the Physician Fee Schedule.

Response: We agree with the commenters on the importance of avoiding potentially disruptive changes in payment for affected interested parties and the need to promote payment stability from year-to-year. This is why we finalized the use of a multi-year transition for the clinical labor update in last year's CY 2022 PFS final rule to help smooth out the changes in payment resulting from the updated data (86 FR 65024). We also note for the commenters that section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. For additional information regarding the phase-in of significant RVU reductions, we direct readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70929). Given the mechanisms already in place to smooth payment changes and promote stability, and considering the need to establish appropriate resource-based valuations, we do not believe the limitation suggested by commenters is warranted.

Comment: Several commenters stated that CMS should prioritize stability and predictability over ongoing updates and temporarily freeze the implementation of further policy updates. These commenters requested that CMS pause the ongoing clinical labor pricing update to avoid significant payment redistributions associated with the pricing update.

Response: We finalized the implementation of the clinical labor pricing update through the use of a 4-year transition in the CY 2022 PFS final rule (86 FR 65024). As we stated at the time, although we recognize that payment for some services will be reduced as a result of the pricing update due to the budget neutrality requirements of the PFS, we do not believe that this is a reason to refrain from updating clinical labor pricing to reflect changes in resource costs over time. The PFS is a resource-based relative value payment system that necessarily relies on accuracy in the pricing of resource inputs; continuing to use clinical labor cost data that are nearly two decades old would maintain distortions in relativity that undervalue many services which involve a higher proportion of clinical labor. As noted above, we also finalized the implementation of the pricing update through a 4-year transition to help address the concerns of the commenters about stabilizing RVUs and reducing large fluctuations in year-to-year payments.

After consideration of the comments, we are finalizing the clinical labor prices as shown in Table 8.

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TABLE 8: Finalized CY 2023 Clinical Labor Pricing

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y2 Phase-In Rate Per Minute	Total % Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	0.255	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	0.310	38%
L030A	Lab Tech/MTA	L033A, L026A	0.30	0.46	0.380	53%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	0.380	38%
L033A	Lab Technician	BLS 29-2010	0.33	0.55	0.440	67%
L033B	Optician/COMT	BLS 29-2081, BLS 29-2057	0.33	0.39	0.360	18%
L035A*	Lab Tech/Histotechnologist	L033A, L037B	0.35	0.60	0.473	70%
L037A	Electrodiagnostic Technologist	BLS 29-2098	0.37	0.44	0.405	19%
L037B*	Histotechnologist	BLS 29-2010	0.37	0.64	0.505	73%
L037C	Orthoptist	BLS 29-1141	0.37	0.76	0.565	105%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	0.455	46%
L037E	Child Life Specialist	BLS 21-1021	0.37	0.49	0.430	32%
L038A	COMT/COT/RN/CST	BLS 29-2057, BLS 29-2055, L051A, BLS 19-4010	0.38	0.52	0.450	37%
L038B	Cardiovascular Technician	BLS 29-2031	0.38	0.60	0.490	58%
L038C	Medical Photographer	BLS 29-2050	0.38	0.38	0.383	0%
L039A	Certified Retinal Angiographer	BLS 29-9000	0.39	0.52	0.455	33%
L039B	Physical Therapy Assistant	BLS 31-2021	0.39	0.61	0.500	56%
L039C	Psychometrist	BLS 21-1029	0.39	0.64	0.517	62%
L041A*	Vascular Interventional Technologist	ASRT Wage Data	0.41	0.84	0.624	104%
L041B	Radiologic Technologist	BLS 29-2034	0.41	0.63	0.520	54%
L041C	Second Radiologic Technologist for Vertebroplasty	BLS 29-2034	0.41	0.63	0.520	54%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	0.525	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	0.530	52%
L043A*	Mammography Technologist	ASRT Wage Data	0.43	0.79	0.611	84%
L045A	Cytotechnologist	BLS 29-2035	0.45	0.76	0.605	69%
L045B	Electron Microscopy Technologist	BLS 29-1124	0.45	0.89	0.670	98%
L045C	CORF social worker/psychologist	BLS 21-1022, BLS 19-3031	0.45	0.70	0.575	56%
L046A	CT Technologist*	ASRT Wage Data	0.46	0.78	0.622	70%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	0.615	62%
L047B	REEGT (Electroencephalographic Tech)	BLS 29-2035	0.47	0.76	0.615	62%
L047C	RN/Respiratory Therapist	L051A, L042B	0.47	0.70	0.585	49%
L047D	RN/Registered Dietician	L051A, BLS 29-1031	0.47	0.70	0.585	49%
L049A	Nuclear Medicine Technologist	BLS 29-2033	0.62	0.81	0.713	32%
L050A	Cardiac Sonographer	BLS 29-2032	0.50	0.77	0.635	54%
L050B	Diagnostic Medical Sonographer	BLS 29-2032	0.50	0.77	0.635	54%
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	0.695	78%
L050D	Second Radiation Therapist for IMRT	BLS 29-1124	0.50	0.89	0.695	78%

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y2 Phase-In Rate Per Minute	Total % Change
L051A	RN	BLS 29-1141	0.51	0.76	0.635	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	0.640	51%
L051C	RN/CORF	L051A	0.51	0.76	0.635	49%
L052A	Audiologist	BLS 29-1181	0.52	0.81	0.665	56%
L053A	RN/Speech Pathologist	L051A, L055A	0.53	0.79	0.660	49%
L054A	Vascular Technologist	BLS 19-1040	0.54	0.91	0.725	69%
L055A	Speech Pathologist	BLS 29-1127	0.55	0.82	0.685	49%
L056A	RN/OCN	BLS 29-2033	0.79	0.81	0.800	3%
L057A	Genetics Counselor	BLS 29-9092	0.57	0.85	0.709	50%
L057B	Behavioral Health Care Manager	BLS 21-1018	0.57	0.57	0.570	0%
L063A	Medical Dosimetrist	BLS 19-1040	0.63	0.91	0.770	44%
L107A	Medical Dosimetrist/Medical Physicist	L063A, L152A	1.08	1.52	1.298	41%
L152A	Medical Physicist	AAPM Wage Data	1.52	2.14	1.832	41%

* Updated for CY 2023

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As was the case for the market-based supply and equipment pricing update, the clinical labor rates will remain open for public comment over the remaining course of the 4-year transition period. We welcome additional feedback on clinical labor pricing from commenters in next year's rulemaking cycle, especially any data that will continue to improve the accuracy of our finalized pricing.

d. Technical Corrections to Direct PE Input Database and Supporting Files

We did not propose any technical corrections to the direct PE input database or supporting files in the proposed rule. However, commenters identified the following issues after we issued the CY 2023 PFS proposed rule:

Comment: Several commenters requested that the SD332 bubble contrast supply, an ultrasound-specific contrast agent, should be removed from the direct PE inputs for CPT codes 76978 (*Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion*) and 76979 (*Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion with separate injection*). Commenters stated that this supply item does not need to be included in the direct PE inputs for these two CPT codes because contrast agents are reported separately using existing HCPCS Level II supply codes, such as Q9950 (*Injection, sulfur hexafluoride lipid microspheres, per ml*).

Response: We appreciate the additional information from the commenters indicating that the SD332 supply is duplicative for CPT codes 76978 and 76979 since the supply is separately reported using HCPCS Level II supply codes. Therefore, we are finalizing the removal of the SD332 supply from these two CPT codes.

In the CY 2020 PFS final rule (84 FR 63102 through 63104), we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020, on an interim final basis for the provision of self-administered esketamine. In the CY 2021 PFS final rule, we finalized a proposal to refine the values for HCPCS codes G2082 and G2083 using a building block methodology that summed the values associated with several codes (85 FR 84641 through 84642). Following the publication of the CY 2021 PFS final rule, interested parties expressed concerns that the finalized PE RVU had decreased for HCPCS codes G2082 and G2083 as compared to the proposed valuation and as compared to the previous CY 2020 interim final valuation. Interested parties questioned whether there had been an error in the PE allocation since CMS had finalized increases in the direct PE inputs for the services.

We reviewed the indirect PE allocation for HCPCS codes G2082 and G2083 in response to the interested party inquiry and discovered a technical change that was applied in error. Specifically, we inadvertently assigned a different physician specialty than we intended (''All Physicians'') to HCPCS codes G2082 and G2083 for indirect PE allocation in our ratesetting process during valuation of these codes in the CY 2020 PFS final rule, and continued that assignment into the CY 2021 PFS proposed rule. This specialty assignment caused the PE value for these services to be higher than anticipated for CY 2020. We intended to revise the assigned physician specialty for these codes to ''General Practice'' in the CY 2021 PFS final rule; however, we neglected to discuss this change in the course of PFS rulemaking for CY 2021. Since we initially applied this technical change in the CY 2021 PFS final rule without providing an explanation, we issued a correction notice (86 FR 14690) to remove this change from the CY 2021 PFS final rule, and to instead maintain the All Physicians specialty assignment through CY 2021. We apologize for any confusion this may have caused.

For CY 2022, we finalized our proposal to maintain the currently assigned physician specialty for indirect PE allocation for HCPCS codes G2082 and G2083 to maintain payment consistency with the rates published in the CY 2020 PFS final rule and the CY 2021 PFS proposed rule. Although we had previously intended to assign the General Practice specialty to these codes, interested parties have provided additional information about these services suggesting that maintaining the All Physicians specialty assignment for these codes will help maintain payment stability and preserve access to this care for beneficiaries. We solicited public comments to help us discern which specialty would be the most appropriate to use for indirect PE allocation for HCPCS codes G2082 and G2083. We note that the PE methodology, which relies on the allocation of indirect costs based on the magnitude of direct costs, should appropriately reflect the typical costs for the specialty the commenters suggest. For example, we do not believe

it would be appropriate to assign the Psychiatry specialty for these services given that HCPCS codes G2082 and G2083 include the high direct costs associated with esketamine supplies. The Psychiatry specialty is an outlier compared to most other specialties, allocating indirect costs at a 15:1 ratio based on direct costs because psychiatry services typically have very low direct costs. Assignment of most other specialties would result in allocation of direct costs at roughly a 3:1 ratio. We requested that commenters explain in their comments how the indirect PE allocation would affect the payment for these services. Specifically, to ensure appropriate payment for HCPCS codes G2082 and G2083, we wanted to get a better understanding of the indirect costs associated with these services, relative to other services furnished by the suggested specialty.

As we noted in the CY 2021 PFS final rule (85 FR 84498 through 84499) and CY 2022 PFS final rule (86 FR 65042), the RAND Corporation was studying potential improvements to our PE allocation methodology and the data that underlie it. We were interested in exploring ways that the PE methodology can be updated, which could include improvements to the indirect PE methodology to address newer services similar to those described by G2082 and G2083 which have a direct to indirect ratio that does not match their most commonly billed specialties. In CY 2022, we agreed with the commenters who supported the proposal to maintain the currently assigned physician specialty (All Physicians) for indirect PE allocation for these codes. After consideration of the public comments, we finalized our proposal to maintain the All Physicians specialty for indirect PE allocation for HCPCS codes G2082 and G2083 for CY 2022.

For CY 2023, we did not make any proposals regarding the assigned physician specialty for indirect PE allocation for HCPCS codes G2082 and G2083; however, we received public comments on this topic from interested parties. The following is a summary of the comments we received and our responses.

Comment: One commenter urged CMS to adopt a clear and recurring process to update, on an annual basis, supply costs for codes G2082 and G2083 with the most recently available wholesale acquisition cost (WAC) data and to include the ''Psychiatry'' specialty type in the allocation of the indirect PE for G2082 and G083. The commenter believed these recommended actions directly support the following two priority CMS initiatives: the CMS Behavioral Health Strategy and an approach to improve the PE methodology within the PFS. The commenter stated that the technical correction for CY 2021 to assign these HCPCS codes to the ''All Physician'' specialty preserved Medicare beneficiary access and was an improvement over the original CMS intent to assign them to the ''General Practice'' specialty but ''demonstrated the sensitive and intricate dependency of Medicare beneficiary access on reimbursement.''

The commenter urged CMS to provide additional insight behind its specialty designation of ''All Physicians'' for HCPCS codes G2082 and G2083, and argued that CMS deviated from its normal practice of using the specialty mix contained in the claims data for these codes. The commenter stated that, while CMS has cited concerns in applying the actual specialty mix, CMS has not provided sufficient information or data to suggest that the rates produced when the ''Psychiatry'' specialty is included produces an inaccurate payment. The commenter also requested that CMS consider the implementation of policies that allow for the construction of specialty blends in unique cases, such as HCPCS codes G2082 and G2083, in which the agency has concerns about applying a service's actual specialty mix. The commenter stated that, based on utilization data published with the CY 2023 PFS proposed rule, over 70 percent of practitioners administering esketamine are psychiatrists. Considering that it is primarily psychiatrists administering esketamine and CMS recognizes the imperative to improve the indirect PE and PFS rate setting methodology for behavioral health services, the commenter recommended a transition of specialty designation for HCPCS codes G2082 and G2083 to its actual specialty mix through a three-year phased-in approach. The commenter recognized CMS' concerns about assigning the Psychiatry specialty for HCPCS codes G2082 and G2083 given the higher supply costs for these services, but recommended that CMS adopt a specialty blend of three-fourths ''Psychiatry'' specialty type and one-fourth ''All Physician'' specialty type. The commenter believed that this specialty blend would result in appropriate reimbursement and acknowledge the role of psychiatrists while also addressing our concerns.

The commenter also stated that in CY 2021, CMS updated the price for the esketamine supply item for these codes using wholesale acquisition cost (WAC) data from the most recent available quarter, but did not again update the price using the latest WAC data in the CY 2022 PFS final rule, or propose to update the price in the CY 2023 PFS proposed rule. The commenter stated that, based on WAC data on submitted invoices for the most recently available quarter, the supply input that describes 56 mg (supply code SH109) for HCPCS code G2082 should be priced at $683.67, and the supply input describing 84 mg of esketamine (supply code SH110) for HCPCS code G2083 should be priced at $1025.50. The commenter urged CMS to align with its prior action and stated intention to address input price updates in future rulemaking by updating the supply pricing for SH109 and SH110 using WAC data annually, and to make clear the additional data or processes interested parties should follow to support annual updates for the esketamine supply items for these codes.

Response: We continue to believe that the All Physicians specialty most accurately captures the indirect PE allocation associated with HCPCS codes G2082 and G2083. We do not assign a blended combination of specialties for any other services and the commenters did not provide new data to support a change in specialty assignment aside from noting that many practitioners who report HCPCS codes G2082 and G2083 are in the Psychiatry specialty. We continue to believe that it would not be accurate to assign the Psychiatry specialty for HCPCS codes G2082 and G2083 due to its outlier status among specialties, whereby Psychiatry allocates indirect costs at a 15:1 ratio based on direct costs as compared to most other specialties having approximately a 3:1 ratio. We do not believe that Psychiatry would be an accurate specialty designation for HCPCS codes G2082 and G2083 given the high direct costs associated with esketamine (which would translate into disproportionately high indirect PE allocation at the 15:1 ratio). We also disagree that these services should be reassigned to a different specialty to offset reductions in payment that result from an unrelated policy proposal (the clinical labor pricing update).

However, to account for the cost of the provision of the self-administered esketamine as a direct PE input, we agree with the commenters that we should update supply costs to reflect the wholesale acquisition cost (WAC) data from the most recent available quarter. For HCPCS code G2082, we are finalizing an updated price of $683.67 for the supply input that describes 56 mg (supply code SH109) and for HCPCS code G2083, we are finalizing an

updated price of $1025.50 for the supply input describing 84 mg of esketamine (supply code SH110) based on the submitted invoices.

After consideration of the public comments, we continue to believe that the All Physician specialty is the most accurate specialty assignment for HCPCS codes G2082 and G2083, and we are not finalizing any changes to the specialty assignment. However, as noted above we are finalizing an increase in the price of the SH109 supply to $683.67 and an increase in the price of the SH110 supply to $1025.50 to reflect the updated market-based prices associated with esketamine. We also received comments on other policies relating to these services that were not addressed in the CY 2023 PFS proposed rule, and which we are not addressing in this final rule. We appreciate the feedback from the commenters and will take it into consideration for possible future rulemaking.

5. Soliciting Public Comment on Strategies for Updates To Practice Expense Data Collection and Methodology

The PE inputs used in setting PFS rates, including both the development of PE RVUs and, historically, the relative shares among work, PE, and malpractice RVUs across the PFS, are central in developing accurate rates and maintaining appropriate relativity among PFS services and overall payment among the professionals and suppliers paid under the PFS. Consequently, the underlying PE data inputs are a consistent point of interest among interested parties. However, unlike other payment systems with cost reporting systems, PFS data inputs are primarily based on exogenous proprietary data that become available as the data are collected. Specifically, we rely on historical survey data (almost all of which is over a decade old), some publicly available data collected for other purposes (for example, Bureau of Labor Statistics (BLS) wage data), recommendations from the American Medical Association and other provider groups, and annual Medicare claims data.

a. History of Updates to PE Inputs

Each year we continue to improve accuracy, predictability, and sustainability of updates to the PE valuation methodology to reduce the risks of possible misvaluation and other unintended outcomes. We have continued to develop policies geared toward providing more consistent updates to the direct PE inputs used in PFS ratesetting, including supply/equipment pricing and clinical labor rates. These efforts to develop these policies should contribute to improved standardization and transparency for all PE inputs used to update the PFS. As we continue our work to improve the information we use in our PE methodology, we issued a general comment solicitation to better understand how we might improve the collection of PE data inputs and refine the PE methodology.

In recent years, we have refined specific PE data inputs using a combination of market research and publicly available data (for example, market research on medical supply and equipment items and BLS data to update clinical labor wages) to update the direct PE data inputs used in the PFS ratesetting process. Last year, we implemented a final transition year for supply and equipment pricing updates and started the first year of a 4-year phase-in update to the clinical labor rates. However, the indirect PE data inputs remain tied to legacy information that is well over a decade old. To build on much needed progress, we now believe indirect PE would also benefit from a refresh that implements similar standard and routine updates. We believe that a data refresh, and use of data sources that receive routine refreshes, would reduce the likelihood of unpredictable shifts in payment, especially when such shifts could be driven by the age of data available rather than comprehensive information about changes in actual costs.

b. Data Collection, Analysis and Findings

In light of feedback from interested parties, CMS has prioritized stability and predictability over ongoing updates, and has taken a measured approach to updating PE data inputs. We have worked with interested parties and CMS contractors over a period of years to study the landscape and identify possible strategies to reshape the PE portion of physician payments. The fundamental issues are clear, but thought leaders and subject matter experts have advocated for more than one tenable approach to updating our PE methodology. Thus, we must balance the various interests of the public, and any path forward should allow for ongoing and routine cycles of PE updates.

Of the various PE data inputs, we believe that indirect PE data inputs, which reflected costs such as office rent, IT costs, and other non-clinical expenses, present the opportunity to build consistency, transparency, and predictability into our methodology to update PE data inputs. The primary source for indirect PE information is the Physician Practice Information Survey (PPIS), fielded by the AMA. The survey was most recently conducted in 2007 and 2008 (reflecting 2006 data). The survey respondents were self-employed physicians and selected nonphysician practitioners.

In general, interested parties have expressed the following concerns regarding CMS's approach to indirect PE allocation:

- CMS seems to rely on increasingly out-of-date data sources, and there is a dearth of mechanisms to update empirical inputs.
- The approach exacerbates payment differentials that possibly create inappropriate variation of reimbursement across ambulatory places of service (for example, significantly higher payments for the same service provided in a hospital outpatient department versus a physician office).
- CMS's method of indirect PE allocation may not accurately reflected variation in PE across different types of services, different practice characteristics, or evolving business models. Beyond these issues, we have also explored other concerns with our indirect PE allocation method in depth in previous rulemaking. For example, refer to our previous comment solicitation and discussion of resource costs for services involving the use of innovative technologies in our CY 2022 PFS proposed rule (86 FR 39125). PE data inputs, and the methodological and evidence-based principles that shape use of such information in the context of reimbursement, are discussed in depth in a RAND Corporation (''RAND'') report prepared for CMS, entitled *Practice Expense Methodology and Data Collection Research and Analysis,* available at *https://www.rand.org/pubs/research_reports/RR2166.html*.[1]

Various interested parties have taken issue with the use of certain costs in our current PE allocation methodology that they do not believe are associated with increased indirect PE. Some interested parties argue that the costs of disposable supplies, especially expensive supplies, and equipment are not relevant to allocating indirect PE; or that similarly, work in the facility setting (for example, work RVUs for surgical procedures) is not relevant to allocating indirect PE,

[1] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. *https://www.rand.org/pubs/research_reports/RR2166.html.*

though they agree that work in the office setting may be relevant to allocating indirect PE.[2] However, we do not believe that there is sufficient, if any, data or peer-reviewed evidence available to definitively show that shifting indirect PE allocations based on the setting of care, or based on specialty, would result in improved allocations of PE that reflect true costs. Further, varying indirect PE allocations based on setting of care or based on specialty might create unintended consequences such as reduced access to care for beneficiaries, or reduced competition and autonomy of small group practices or individual clinicians whose revenue is based in part on services furnished under contract in the facility setting.

We believe it is necessary to establish a roadmap toward more routine PE updates, especially because potentially improper or outdated allocation of PE across services may affect access to certain services, which could exacerbate disparities in care and outcomes. Establishing payments that better reflect current practice costs would mitigate possible unintended consequences, such as labor market distortions due to indirect cost allocations that do not reflect the current evolution of health care practice.[3] Interested parties have reiterated their desire for CMS to move away from the current PE allocation approach and continued to raise concerns with CMS's methodology and the underlying PE data inputs. In response to these and other concerns, we continue to review the methodology we use to establish the PE RVUs and to identify refinements. As part of this effort, we have contracted with RAND to develop and assess potential improvements in the current methodology used to allocate indirect practice costs in determining PE RVUs for a service, model alternative methodologies for determining PE RVUs, and identify and assess alternative data sources that CMS could use to regularly update indirect practice cost estimates.[4]

In this final rule, we are signaling our intent to move to a standardized and routine approach to valuation of indirect PE and we solicited feedback from interested parties on what this may entail, given our discussion above. We would propose the new approach to valuation of indirect PE in future rulemaking.

We solicited comment on the following topics related to identification of the appropriate instrument, methods, and timing for updating specialty-specific PE data:

- Potential approaches to design, revision, and fielding of a PE survey that foster transparency (for example, transparency in terms of the methods of survey design, the content of the survey instrument, and access to raw results for informing PFS ratesetting); and
- Mechanisms to ensure that data collection and response sampling adequately represent physicians and non-physician practitioners across various practice ownership types, specialties, geographies, and affiliations.

We also solicited comment on any alternatives to the above that would result in more predictable results, increased efficiencies, or reduced burdens. For example:

- Use of statistical clustering or other methods that would facilitate a shift away from specialty-specific inputs to inputs that relate to homogenous groups of specialties without a large change in valuation relative to the current PE allocations.
- Avenues by which indirect PE can be moved for facility to non-facility payments, based on data reflecting site of service cost differences.
- Methods to adjust PE to avoid the unintended effects of undervaluing cognitive services due to low indirect PE.
- A standardized mechanism and publicly available means to track and submit structured data and supporting documentation that informs pricing of supplies or equipment.
- Sound methodological approaches to offset circularity distortions, where variable costs are higher than necessary costs for practices with higher revenue.

We also solicited comment on the cadence, frequency, and phase-in of adjustments for each major area of prices associated with direct PE inputs (Clinical Labor, Supplies/Equipment). We requested that commenters address the following:

- Whether CMS should stagger updates year-to-year for each update, or establish ''milestone'' years at regular intervals during which all direct PE inputs would be updated in the same year.
- The optimal method of phasing in the aggregate effect of adjustments, such that the impacts of updates gradually ramp up to a full 100 percent over the course of a few years (for example, 25 percent of the aggregate adjustment in Year 1, then 50 percent of the aggregate adjustment in Year 2, etc.).
- How often CMS should repeat the cycle to ensure that direct PE inputs are based on the most up-to-date information, considering the burden of data collection on both respondents and researchers fielding instruments or maintaining datasets that generate data.

We received public comments on data collection, analysis and findings. The following is a summary of the comments we received and our responses.

Comment: Most commenters that responded to this RFI recommended that CMS delay any change to update the indirect PE survey inputs. Many commenters urged CMS to wait for AMA data collection efforts prior to implementing changes. In responding to our RFI, the AMA RUC underscored that CMS wrote in this year's proposed rule that the AMA PPIS continues to be the best available source of data necessary for the purpose of calculating indirect PE. AMA also points to the fact that CMS has relied on AMA physician cost data for 50 years in updating the MEI and 30 years updating the RBRVS. Additionally, the RUC urged that CMS continue to work with the AMA and various specialty societies involved in the previous data collection effort, and wait for an updated set of data to become available for use. The AMA indicated that it has continued work on updates and would likely be ready by early CY 2024 with refreshed data. One commenter submitted a jointly-signed letter that did not support the AMA RUC approaches, and described a different means of data collection and analysis for updating the PE methodology. In addition to emphasizing some of the same themes noted in findings from RAND's review of the PE landscape, the letter recommended that CMS form an expert advisory group, multidisciplinary in composition, and backed with a dedicated research and development team of CMS staff, to support CMS' strategic plans to update PFS ratesetting. In this letter, the commenter also posited that indirect allocations would eventually be unnecessary, as the methodology could be evolved toward an entirely different means to capture actual costs of services. Overall, we received few direct responses to many

[2] Kazungu, Jacob S., Edwine W. Barasa, Melvin Obadha, and Jane Chuma. ''What Characteristics of Provider Payment Mechanisms Influence Health Care Providers' Behaviour? A Literature Review.'' *The International Journal of Health Planning and Management* 33, no. 4 (October 2018): e892–905. *https://doi.org/10.1002/hpm.2565*.

[3] Laugesen, Miriam J. ''Regarding 'Committee Representation and Medicare Reimbursements: An Examination of the Resource-Based Relative Value Scale.' '' *Health Services Research* 53, no. 6 (December 2018): 4123–31. *https://doi.org/10.1111/1475-6773.13084*.

[4] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. *https://www.rand.org/pubs/research_reports/RR2166.html*.

of the specific prompts included in our request for information.

Response: We reiterate that we continue to believe that the current AMA PPIS data does represent the best available source of information at this time. However, as we continue to engage with a broad range of perspectives from interested parties who frequently ask for CMS policy to better reflect rapidly changing health care costs, we acknowledge, in consideration of these perspectives and our work to analyze these issues, that these concerns may be addressed by consistent and transparent data refreshes.

We remain interested in possible alternatives to use of a sole source of data. We believe that transparency and repeatability should be key principles for examining future work to update indirect PE inputs. We have clear agreement among interested parties that the economic and medical landscapes have changed, and rapidly. Our intent remains to seek data that capture such changes on a more frequent basis, and allow for others to explore and study how best to assess and account for changes with more rapid feedback loops. Conversely, we understand that the competitive marketplace may create a dynamic whereby some market participants receive revenue for the licensing and sharing of proprietary information itself. We believe it remains important to avoid interference with this type of business arrangement between vendors and their customers, yet, we also believe that there is a strong public interest to support open, transparent, and low-cost means to conduct research on these topics. For example, we are not aware of any independent, third-party, peer-reviewed research focused on the characteristics of the health care labor market in light of advancements in automation (for example, empirical analysis of how software implementation may have a causal link to changes in the health care labor market). Simply put, there are no available studies that adequately answer the question, with sufficient predictive power and adequate empirical data, of how much clinical labor is saved, or replaced, by use of automation, in the context of furnishing practitioner services. Further, many, if not all examinations of automation and its effects on labor take a far broader focus than health care workforce only, and mainly use anecdotal information, with conclusions or hypotheses that focus on job gains/losses. We note that many commenters highlighted themes this year focusing on labor shortages, rather than labor surplusage. The comments that noted refreshed survey data alone would address the need for more precise, and up-to-date, allocations of indirect expenses seem discordant with other comments we received about updating our PE methodology to account for current advancements in automation, and associated software costs. Therefore, there are a number of competing concerns that CMS must take into account when considering updated data sources, which also should support and enable ongoing refinements to our PE methodology.

For these reasons, it is possible that CMS would look to using verifiable, more objective data sets in the future to supplement or augment survey data alone. Such action would be similar to how certain specialty data are used in current indirect PE calculations, and sourced from specialty societies themselves, as required by statute, in some cases as PPIS data were not available. Alternatively, we may explore the use of data already in the public domain. We believe that fast-moving changes to the distribution of costs and use of evolving technology, and more generally the innovations in how vendors support practices, reshape indirect expenses in ways that would require flexible but standardized methods to account for these on a more frequent basis in our ratesetting methodology.

We reiterate our needs described in our initial discussion for this RFI. We note that this interest to develop a roadmap for updates to our PE methodology is underpinned by a need to have better understanding of repeatability and reproducibility of results, as we move toward more consistent and frequent data collection. Some commenters expressed concerns over bias and validity. We believe some of those concerns may be alleviated by having means to refresh data and make transparent with more accuracy and precision how the information affects valuations for services payable under the PFS.

Further, we note that it is possible that with the current timing for AMA's planned updates, we would be unable to refresh data for several years. This would result in CMS using data nearly 20 years old to form indirect PE inputs used to set rates for services on the PFS. As these survey data are static inputs, and leverage only the responses gathered at the time of collection, which are applied using a methodology without any dynamic variables, this is quite distinct from each of the MEI and various other inputs in PE methodology.

We believe both the somewhat stale and static aspects of the PPIS, along with expected timing for updates is significantly at tension with the feedback we receive on a regular basis. Consistently, a broad range of perspectives across various interested parties frequently ask for CMS to better reflect costs in what has been a rapidly changing health care payment landscape. The medical community and others continue to point to shortcomings in our ratesetting methodology, which may be improved by consistent and transparent data refreshes.

Additionally, we acknowledge that some hold disparate points of view about the above process of updating our PE methodology. We note that part of the public comment process aims to encourage thinking and build consensus, or identifies a lack of consensus. We appreciate the dialogue, multiple perspectives, and encourage that the broader national community of health policy thought leaders, health economists, and health systems researchers, all continue to have such conversations with one another and with CMS. A diversity of perspectives is important to foster a more robust set of options for the best available path forward.

We again thank commenters for submitting feedback on our RFI. We reiterate that our RFI does not contain any specific proposals for CY 2023. We will consider possible proposals in future rulemaking.

c. Changes to Health Care Delivery and Practice Ownership Structures, and Business Relationships Among Clinicians and Health Care Organizations

Market consolidation, and shifts in workforce alignment, as well as an evolution in the type of business entities predominant in health care markets, all suggest significant transformation in the composition and proportions of practice expenses required to furnish care. These evolving conditions collectively highlight the need for a comprehensive update to PE data inputs, and possibly the PE methodology as a whole.[5] Ideally, more comprehensive PE data inputs and a different PE calculation methodology would better account for indirect/overhead costs, current trends in the delivery of health care, the use of machine learning technology, and EHRs, and the cost differentials in

[5] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. *https://www.rand.org/pubs/research_reports/RR2166.html.*

independent versus facility-based practices.

We solicited comment on current and evolving trends in health care business arrangements, use of technology, or similar topics that might affect or factor into indirect PE calculations. We are interested in learning whether any PE data inputs may be obsolete, unnecessary, or misrepresentative of the actual costs involved in operating a medical practice.

We received public comments on current and evolving trends in health care business arrangements, use of technology, or similar topics that might affect or factor into indirect PE calculations. The following is a summary of the comments we received and our responses.

Comment: A few commenters responding to our prompt to explore avenues by which indirect PE can be moved for facility to non-facility payments, based on data reflecting site of service cost differences, suggested that indirect PE inputs should not be part of payment for the facility rate of payment.

Commenters explained that because the facility bears the indirect costs for provision of services at the facility, and the physician or practitioner would receive indirect PE allocations for any in-office services, the indirect PE portion of the facility fee for a physician service is unwarranted.

Response: We note that the face value of a change that would reduce the indirect PE portions of our current facility fees for physicians' services to zero may have merit. We have open questions about this feedback, which we will explore further in our ongoing research. We believe, and related feedback from interested parties suggests, there are two considerable shifts in today's healthcare business models. First, many physicians and NPP's have become employed staff, versus independent practitioners. Second, the landscape includes far more variation in the ways that organizations interact and contract for clinical staff and auxiliary personnel, and structure their compensation. We would aim to better understand whether potentially reducing to zero any indirect PE portion that is part of the facility fee for physician services may or may not reduce competition, or have the unintended effect of favoring certain forms of arrangements over others.

Further, before proposing any policy, we would need to understand whether the policy could address related open questions. Our work with RAND to explore the relationship between different types of indirect costs and direct cost inputs remains one of few empirical efforts to examine the issue in-depth. In this year, and in previous years, when we have requested similar information from the public, we continue to receive anecdotal, if any evidence, when feedback from commenters aims to take issue with findings in the RAND studies.

d. Unintended Consequences and Missing Information

We solicited comment on additional information that we may have not considered or discussed above about updating and maintaining PE data inputs, as well as any unintended impacts (or positive outcomes) that could result from changes to the overall strategy. We are especially interested in public comment on any concerns about beneficiaries' access to care, possible consolidation of group practices, or burden on small group or solo practitioners. We are also interested in public comments on any collateral program integrity or quality issues that could arise from potential updates. We requested that any respondents who provide feedback ensure that the response includes discussion of any possible health equity impacts.

We received public comments on unintended consequences and missing information. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed concern that topics of AI, a related evolution of software and technology used to support provision of services, and ties to health equity are not well-suited for the process of updates to our annual rulemaking cycle. Commenters expressed concerns that the public comment process alone is not sufficient to provide information, and requested a separate RFI. We received a similar response from many interested parties that question how CMS has in the past, and will in the future, address definition of topics and terms that shape our PE inputs.

Response: We encourage interested parties to continue to provide feedback and suggestions to CMS that in general, give an evidentiary basis to shape optimal PE data collection and methodological adjustments over time. Submissions should discuss the feasibility and burden associated with implementation of any suggested adjustments, and should highlight opportunities to optimize the cadence, frequency, and phase-in of resulting adjustments. In the interim, we will continue to consider ways that we may engage in dialogue with interested parties to better understand how to address possible long-term policies and methods for PFS ratesetting.

6. Soliciting Public Comment on Strategies for Improving Global Surgical Package Valuation

In preparation for future rulemaking, we solicited public comment on strategies to improve the accuracy of payment for the global surgical packages (herein referred to as ''global packages') under the PFS. Currently, there are over 4,000 physicians' services paid as global packages under the PFS. Global packages generally include the surgical procedure and any services typically provided during the pre- and postoperative periods (including evaluation and management (E/M) services and hospital discharge services). There are three types of global packages:

- The 0-day global package, which includes the procedure and the preoperative and postoperative physicians' services on the day of the procedure.
- The 10-day global package, which includes services on the day of, and 10 days after, the procedure.
- The 90-day global package, which includes services furnished one day prior to the procedure, and on the day of, and 90 days immediately following the day of the procedure.

More detail about how global packages are billed and what activities are included may be found in Chapter 12, Section 40, of the Medicare Claims Processing Manual (Pub. 100–04).

We have applied the concept of global payment for some procedures since the inception of the PFS on January 1, 1992 (54 FR 59502). However, in the past decade we have engaged with interested parties regarding numerous concerns about the accuracy and validity of the valuation of global packages, with particular attention paid to the E/M visits included in the services. We have made previous requests for public feedback on global packages, including solicitations for information or data that could be used to help support more accurate valuations. We now wish to expand on our conversations with the public, considering the current status of a multi-year data collection and analysis project, as well as ongoing changes we have made to payments for other types of patient care that may impact the global packages.

a. History of Global Valuation Discussion

In the CY 2013 PFS proposed rule (77 FR 44737 through 44738), we discussed two reports released by the HHS Office of the Inspector General in 2005 and

2012 with findings that practitioners were performing fewer E/M postoperative visits than had been included in the valuation for these global packages, suggesting that Medicare was paying for care that was not being delivered. In response to the concerns raised by the OIG reports, we solicited public feedback on methods of obtaining accurate and current data on E/M services furnished as part of a global package. We summarized public comment in the CY 2013 PFS final rule (77 FR 68911 through 68913).

In the CY 2015 PFS proposed rule (79 FR 40341), we delved into barriers to accurate valuation of global packages, especially as compared to other forms of bundled payments made under the inpatient or outpatient prospective payment systems. In addition to the ongoing concerns about whether E/M visits presumed to be furnished in connection with global packages were actually being performed by the physician receiving the global package payment, we noted issues such as:

- E/M services in the global period that occur post-discharge are valued with PE values associated with follow-up visits in the physician's office. Many of these follow-up visits may occur in a hospital outpatient department where the physician may not incur many PE costs.
- The direct PE inputs often differ slightly between an E/M service furnished in a global period and a stand-alone E/M service. For example, follow-up visits for certain surgeries may include specialized clinical labor such as an RN rather than a general nurse blend.
- The types of physicians furnishing a specific service dictate the direct and indirect percentages, as well as the indirect practice cost index, in the PE methodology. Most surgical specialties have a lower direct percentage mix, resulting in higher indirect costs that extend to the E/M visits in the global periods.
- Because the E/M visits embedded in the global package are not reported separately and do not appear in claims data, it is difficult to quantify the number and level of E/M services furnished in connection with global packages under the fee-for-service system.
- In some cases we have limited billing of the 10- and 90-day global packages in conjunction with some of the payment policies intended to encourage coordination of care through payments for non-face-to-face services, such as transitional care management and chronic care management, because of presumed overlap between these services.

To address these concerns, we solicited comment and finalized a policy in the CY 2015 PFS final rule (79 FR 67586) intended to, over a period of several years, transition all services with 10-day and 90-day global periods to 0-day global periods. As stated in the CY 2015 PFS final rule, we believed it would be more accurate to value the surgical procedure-day services separately from postop E/M visits, and would avoid potentially duplicative or unwarranted payments. For our full discussion and rationale, refer to 79 FR 67586 through 67591. Implementation of this policy, however, was halted by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 110–14). Section 523(a) of the MACRA amended section 1848(c)(8) of the Act to prohibit the Secretary from implementing the transition policy finalized in the CY 2015 PFS final rule. The amendments to section 1848(c)(8) of the Act also require CMS to collect additional data on how best to value global packages and to reassess every 4 years the continued need for this data collection. Section 1848(c)(8) of the Act directs CMS to use the information collected to improve the accuracy of valuation of these services under the PFS starting in CY 2019. (Refer to the CY 2016 PFS final rule at 80 FR 70915 for additional discussion of these requirements.)

In response to the statutory requirements as added by section 523(a) of the MACRA, we engaged in multiple discussions with interested parties about methods of data collection and analysis, including through public comment solicitation in the CY 2016 PFS proposed rule (80 FR 41707) and CY 2017 PFS proposed rule (81 FR 46191), a national listening session, and a town hall meeting. (Materials for the January 20, 2016 listening session are available at *https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2016-01-20-MCRA-Presentation.pdf*. The transcript of the town hall meeting held August 25, 2016 is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2017-PFS-FR-Townhall.pdf*.) In the CY 2017 PFS final rule (81 FR 80209 through 80213), we finalized a claims-based process to collect data from practitioners on both the number and level of postoperative visits furnished as part of the 10- and 90-day global packages. We also contracted with RAND to support this data collection and analysis.

b. Data Collection, Analysis, and Findings

In 2019, RAND issued two reports based on its analysis of the data collected through the data collection process we established. The reports examined, using claims-based and survey-based data, the number of postoperative visits furnished during the 10- and 90-day global periods for certain high-volume procedures and the level of visits furnished for certain procedures. (Complete details about the data collected are discussed in the CY 2017 PFS final rule starting at 81 FR 80212, the CY 2020 PFS final rule at 84 FR 62857, and in the reports themselves, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-*.) Notably, RAND's analysis found that, according to claims-based data, the reported number of E/M visits matched the expected number (included for purposes of PFS valuation) for only 4 percent of reviewed 10-day global packages and 38 percent of reviewed 90-day global packages. Based on these analyses, RAND released a third report that analyzed the current valuation of global packages based on the difference between the number of postoperative E/M visits observed via the claims-based data collection process and the expected number of such E/M visits. The report modeled how valuation for global packages would change by adjusting the work RVUs, physician time, and direct PE inputs to reflect the observed number of E/M visits. The report provided hypothetical valuations for the global packages based on these adjustments. These three RAND reports were made available to the public and are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection*.

The RAND reports were shared with the public, and we received public comment about these reports in the CY 2020 PFS final rule (84 FR 62866). Public commenters raised concerns about the findings in the reports, including questions as to whether the E/M visit data were collected from a true representative sample of practitioners, and various other challenges to the validity of the RAND methodology. Other members of the public, however, were supportive of our overall efforts to collect and analyze the data, and supplied additional data similarly suggesting that the 10- and 90-day global packages are overvalued. In 2021, RAND responded to the CY 2020 public comments that were critical of

the methodologies used in the three earlier reports in a separate report entitled, ''Responses to Comments on RAND Global Services Reports,'' which is available at *https://www.rand.org/content/dam/rand/pubs/research_reports/RR4300/RR4314-1/RAND_RR4314-1.pdf/*.

While some interested parties have challenged the methodology or conclusions of the RAND reports, we have not yet received data suggesting that postoperative E/M visits are being performed more frequently than indicated by the data collected and analyzed in the RAND reports. We continue to be concerned that our current valuations of the global packages reflect certain E/M visits that are not typically furnished in the global period, and thus, are not occurring. We also believe that RAND has adequately responded to critiques of its methodologies and findings. However, as part of our ongoing assessment of our data collection process, we continue to welcome any comments from the public on ideas for other sources of data that would help us to assess global package valuation (including the typical number and level of E/M services), as well as our data collection methodology and the RAND report findings. We received some public comments in our request for comments on possible additional data sources and on our data collection methodology. These comments are summarized as follows:

Comment: Some commenters supported the findings and methodology of the RAND reports. Several commenters stated that the RAND's findings regarding E/M visit performance aligned with their own anecdotal observations and experiences. However, other commenters expressed skepticism of the RAND report findings and methodology, and many urged us to continue to rely on RUC valuations of global packages (including the number of embedded E/M visits included in the RUC surveys.) Several commenters observed that getting truly accurate information from claims data may be difficult; one commenter pointed out that since work done by NPPs or clinical staff is often not reported separately, it is difficult to get a complete picture of postoperative work. As in previous public discussions, commenters urged CMS to continue to examine claims data and electronic health records, or obtain postoperative E/M information through direct surveys of practitioners. Several commenters noted that we have spent many years performing data collection in response to the MACRA requirements, and one commenter requested that we cease our data collection efforts to avoid any additional burden on practitioner. Many commenters urged us to continue to work in collaboration with practitioners and other impacted parties to identify sources of postoperative E/M data and to maintain transparency about any additional collection efforts.

Response: We found that the comments we received, particularly those critical of the RAND reports and methodology, echo the feedback we received several years ago when we shared the RAND reports for public comment. Please see the discussion of the RAND reports and findings in the CY 2020 PFS final rule (84 FR 62866) and RAND's responses to the CY 2020 public comments in the RAND report entitled, ''Responses to Comments on RAND Global Services Reports,'' which is available at *https://www.rand.org/content/dam/rand/pubs/research_reports/RR4300/RR4314-1/RAND_RR4314-1.pdf/*. We note that we did not receive new data that might either affirm or contradict RAND's overall findings regarding E/M performance. We agree with commenters' observations that we have spent many years collecting and analyzing data regarding E/M performance in response to the MACRA requirements and other public concerns about the valuation of globals. While we will continue to evaluate potential sources of data regarding E/M performance, we agree with commenters who suggest that the overall lack of transparency within global packages can make identifying the nature of postoperative care provision difficult and continues to call into question the accuracy of globals that have been valued through standard valuation processes.

c. Changes to Health Care Delivery and Payment for E/M Services

Since the inception of the PFS 30 years ago, there have been significant changes in health care, including improvements in medical and information technology, new models of health care delivery and coordination between multiple clinicians furnishing care to a single patient, and an expanding beneficiary population. (For information on Medicare service utilization, beneficiary demographics, provider characteristics, and payment models, please visit the resources at *data.cms.gov*.) We asked to hear from the public on whether the postoperative health care landscape has changed in ways that impact the relevance of the global packages.

We believe that changes to health care delivery may impact proper valuation of global services. We solicited comment on whether changes to health care delivery, including changes in coordination of care and use of medical technology over the past 3 decades, as well as during the recent PHE, have impacted: the number and level of postoperative E/M visits needed to provide effective follow-up care to patients; the timing of when postoperative care is being provided; and who is providing the follow-up care. We have formed hypotheses that some beneficiaries are not receiving the number of postoperative visits that were contemplated when valuing the global surgical packages or are not receiving any follow-up E/M visits at all during global periods either because the physician who performed the surgical procedure has determined they are unnecessary (perhaps due to improvements in medical technology or evolution in standards of care) or as the result of more comprehensive discharge planning. It has also been suggested by some interested parties that physicians are, in fact, performing the number of postoperative visits that were contemplated when valuing the global surgical packages, but the visits may, for various reasons, be scheduled outside the global period. Others have suggested that physicians are, without formally transferring follow-up care to another clinician, instructing patients to follow up with another physician or NPP (such as the patient's primary care physician or other practitioner), and that the other clinician then furnishes and bills for E/M services furnished for postoperative care (whether the care is performed during or after the global period). We appreciate comments on these ideas, and on other factors not mentioned here that could affect the ways that postoperative E/M care is provided.

We also solicited comment on whether, or how, recent changes in the coding and valuation of separately billable E/M services may have impacted global packages. One change is the expansion of payment for non-face-to-face care management services. Historically, an advantage of global packages was that they compensated physicians for non-face-to-face work related to the patient's transition from the hospital to the community, or management of other health care needs following a procedure or serious illness. Over the years, we have implemented payment for many care management services to better reflect non-face-to-face time spent by physicians and clinical staff on behalf of patients with complex health care needs, including transitional care management services in CY 2013 (77 FR 68978); chronic care

management in CY 2015 (78 FR 74414) and CY 2019 (83 FR 58577); complex chronic care management in CY 2017 (81 FR 80244); and principal care management in CY 2020 (84 FR 62962). We solicit comment on whether global packages, and especially those with 10- and 90-day global periods, continue to serve a purpose when physicians could otherwise bill separately not only for the postoperative E/M visits they furnish, but also for aspects of postoperative care management they furnish for some patients. We also would like to hear generally what, if any, components of preoperative or postoperative care are currently only compensated as part of payment for global packages.

We have also heard from some interested parties who believe that recent changes to the coding and valuation of standalone office and outpatient E/M visits finalized in the CY 2021 PFS final rule have skewed the relativity between these visits and the E/M visits included in the current global package valuations (which were not modified in response to the coding and valuation changes). In the CY 2020 PFS final rule (84 FR 62851 through 84 FR 62854), we finalized new—and generally increased, RVUs for the CPT-revised office and outpatient E/M code set. Some commenters encouraged us to increase the value of the E/M visits included in the global surgical packages commensurate with the increased RVUs for the standalone E/M visits. However, we declined to do so, noting that at the time that it was unclear whether it would be appropriate to treat the E/M visits reflected in global packages as discrete components of the package (in other words, to use a building-block approach to calculating the value of the service, versus valuing the services using the more holistic magnitude estimation, or possibly another approach.) Furthermore, we cited the uncertainty as to whether the E/M services included in valuing the global packages are typically furnished as part of global surgery services, reasoning that if the number and level of E/M services for global packages is not appropriate, adopting increases in the value of E/M services in global surgery codes would exacerbate rather than ameliorate any potential relativity issues. (Refer to the CY 2020 PFS final rule at 84 FR 62856 through 62860 for a complete summary of comments and our responses on the topic of increasing the value of E/M visits included in the global packages.) We welcomed additional comments on the perceived misalignment between the E/M visits included in global packages and separately billable E/M services, including thoughts on how this current tension reflects on global payment valuation and the appropriate methodology for determining appropriate values for global packages.

We received some public comments on whether changes to health care delivery and payment for E/M services may impact the performance of E/M visits or overall relevance of E/M visits. The following is a summary of the comments we received and our responses.

Comment: Several commenters noted that while patients in general seem in greater need of critical care, there is also (from various commenters' perspective) either increasing opportunity or mounting pressure on practitioners to discharge patients from hospitals and arrange at-home care after surgeries. Many commenters stated that postoperative care provided by the proceduralists should still be considered a best practice. However, a few commenters agreed with some of our hypotheses—namely that for clinical reasons patients may not need to return for in-person postoperative care within the global period, or that scheduling conflicts may make timely return difficult. A few commenters also agreed that patients may, for reasons of convenience, receive some postoperative care from community practitioners rather than returning to the hospital where the surgical procedure was performed. Some commenters also suggested that there may be clinical reasons why it is better for a patient to receive postoperative care from a practitioner or NPP other than the proceduralist, such as in circumstances when the patient needs long-term or specialized postoperative care outside the expertise of the proceduralist. Overall, commenters expressed ambivalence about the impact the PHE and use of telehealth has had on postoperative care. A few commenters noted that some aspects of postoperative care—including sharing of test results or consultations—can be done via telehealth, while others described types of postoperative care that can only be done in-person. Commenters also expressed doubt about the impact of expanded payments for non-face-to-face services, noting that payments for care management or other non-face-to-face services do not include all post-surgical conditions and do not address in-person care.

Regarding our questions about the overall relevance of global packages, some commenters stated that paying for postoperative care as standalone visits would ensure that Medicare was only paying for the care that was being delivered. A few commenters suggested that postoperative care should be not only paid for separately, but paid at a higher rate. Other commenters stated that global packages continue to be necessary because they reduce administrative burden on practitioners and ensure payment of care provided by NPPs and clinical staff.

Response: While we did not receive a great deal of feedback on our specific request for information as to whether global packages are still relevant, we believe the information we received demonstrates that there may be variations in patients' individual postoperative care needs. While we agree with commenters that in-person visits with the proceduralist is the standard of care on which global packages were based, we will continue to examine whether this specific model of postoperative care is still necessary or relevant for all procedures.

Comment: Many commenters provided input on the valuation of the E/M visits embedded in global packages as compared to standalone E/M visits. Although commenters did not provide feedback on whether the misalignment reflects on the relevance of surgical packages, many commenters suggested that we should increase the value of global packages to reflect the increase in standalone E/M visits (both the office/outpatient increases finalized in CY 2020 at 84 FR 62851 through 84 FR 62854, and increases to certain hospital inpatient E/M visits proposed in CY 2023 at 87 FR 45993.) Some commenters suggested that the data collection requirement in the MACRA amendments to the statute does not preclude CMS from applying such increases to all global packages. Other commenters, however, agreed with our decision not to increase the global packages pending our inquiry into the performance of postoperative E/M visits.

Response: We direct commenters to the CY 2020 PFS final rule (84 FR 62851 through 84 FR 62854), where we discussed similar concerns. We continue to disagree with commenters' interpretation of the MACRA amendments. We note that section 1848(c)(8) of the Act, as amended by section 523(a) of the MACRA (Pub. L. 110–14), directs CMS to use the information collected to improve the accuracy of valuation of these services specifically requires that we use the data we obtain through data collection to revalue the global packages. Our data currently suggests that at least some global packages are inaccurately, revalued, and until we identify data that demonstrates otherwise, we do not believe it would be appropriate to apply

an across-the-board adjustment to the packages that is not supported by data. Additionally, we are also working to reconcile public recommendations that we revalue global packages on a holistic or case-by-case basis (discussed in greater detail in section II.B.6.d. of this final rule) with recommendations that we apply across-the-board increases to all global packages.

d. Strategies To Address Global Package Valuation

Consistent with the discussion above, we continue to believe that: (1) there is strong evidence suggesting that the current RVUs for global packages are inaccurate; (2) many interested parties agree that the current values for global packages should be reconsidered, whether they believe the values are too low or too high; and (3) it is necessary to take action to improve the valuation of the services currently valued and paid under the PFS as global surgical packages.

We would like to re-engage with the public about whether the global packages are indeed misvalued, and if so, what would be an appropriate approach to valuation. We have previously sought assistance from the public on possible methods of revaluation, such as in the CY 2015 PFS final rule (79 FR 67586).

As noted in the ''Data Collection, Analysis, and Findings'' section above (section II.B.6.b.), RAND has provided a comprehensive roadmap for a possible revaluation strategy. (See specifically the RAND report, ''Using Claims-Based Estimates of Postoperative Visits to Revalue Procedures with 10- and 90-Day Global Periods,'' available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-*. We solicited additional input on the RAND methodology, including advantages and drawbacks of applying the RAND methodology to revaluation (in addition to previous feedback that was provided by the public in the CY 2020 PFS final rule at 84 FR 62867). We also requested input on specific alternatives, including: (1) requesting the RUC to make recommendations on new values; or (2) another method proposed by the public.

We solicited feedback from the public on possible strategies for a revaluation process for global services. We believe that the available information provided in the RAND reports (discussed in section II.B.6.b. of this final rule and available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-*) indicates that there is a mismatch between the value of the global package and work being performed. In particular, it appears that for some services, the number of postoperative visits typically furnished by the billing physician is much lower than what was reflected in the global package value, and thus we believe it may be necessary to revalue those services. (As noted in section II.B.6.b. of this final rule, RAND's analysis found that the reported number of E/M visits matched the expected E/M visits for only 4 percent of reviewed 10-day global packages and 38 percent of reviewed 90-day global packages. We referred specifically to the RAND report, ''Claims-Based Reporting of Postoperative Visits for Procedures with 10- or 90-Day; Global Periods—Updated Results Using Calendar Year 2019 Data'' available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-*). Because there are a large number and volume of services paid as global packages, we must consider the resources needed to revalue even a subset of the global packages, as well as the impacts across the PFS and healthcare delivery system in general if we were to change the values of a significant number of services at one time. We considered various approaches we could pursue, such as: (1) revaluing all 10- and 90-day global packages at one time (perhaps with staggered implementation dates); (2) revaluing only the 10-day global packages (because these appear to have the lowest rate of postoperative visit performance, per RAND's analysis of claims data); (3) revaluing 10-day global packages and some 90-day global packages (such as those with demonstrated low postoperative visit performance rates as identified in RAND's analysis of these services); or (4) relying on the Potentially Misvalued Code process to identify and revalue misvalued global packages over the course of many years. (We noted that regardless of whether we review particular global packages as part of a specific revaluation strategy, the public may always nominate any global packages to be reviewed through the Potentially Misvalued Code process; refer to the description of the Potentially Misvalued Code process in section II.C. of this final rule.) We solicited comment on any of the strategies identified in this paragraph, as well as any additional ideas members of the public may have that would address the concerns described above about valuation of global packages. We also solicited comment on ancillary considerations including timing considerations for implementation of any future strategy (such as whether to have staggered effective dates for new valuations and what criteria to use if assigning staggered effective dates.)

We also solicited comment on additional considerations affecting valuation of global services that may not have been thoroughly explored in previous public comment opportunities. For instance, we are aware that some interested parties are concerned that not enough attention has been paid to the value of preservice work bundled into the global payment, which could affect accurate valuation of 10- and 90-day global packages, as well as the value of the service if it is transitioned to a 0-day global. We solicited additional information about this concern, as well as any other concerns about valuation not otherwise mentioned here.

We received public comments on strategies to address global package valuation. The following is a summary of the comments we received and our responses.

Comment: Some commenters agreed that global surgical packages are misvalued and encouraged CMS to revalue the packages in order to reduce the impacts of improper valuation on the relative value scale. A few commenters agreed that packages were misvalued, but suggested we continue to work with impacted parties to find a method for revaluation. Other commenters stated that they do not believe that global packages were misvalued or, if they are misvalued, they should be revalued on a holistic and case-by-case basis using the RUC process or the Potentially Misvalued Code process. A few commenters suggested that CMS and the RUC collaborate on a specific method to revalue global packages. Commenters also noted that revaluing through the RUC process could take a number of years and may present resource challenges.

We received diverse comments on approaches for revaluing the codes, including revaluing all 10- and 90-day packages, revaluing some 10- and 90-day packages, or focusing just on the 10-day packages. Commenters who recommended focusing on the 10-day packages suggested that this would address services with lower demonstrated postoperative E/M visit rates, and would provide us with insight about revaluation that could then be applied to the 90-day packages as needed. Other commenters made suggestions including phasing out global packages by not valuing new CPT codes as globals, or changing the length

of global periods. While one commenter was in favor of revaluing all packages at one time, many commenters suggested revaluing over a number of years to avoid too much disruption to the relative value scale. One commenter suggested we wait until after the conclusion of the PHE to revalue any packages.

Response: We believe that the spectrum of comments demonstrates that there is not, at this time, clear public consensus on this issue or the preferred strategy for valuing globals. We will consider the specific strategies proposed by the commenters and the concerns regarding impact on the relative value scale and the resources that would be required to revalue these codes.

e. Other Payment Structure Changes, Unintended Consequences, and Missing Information

We solicited public comment on any other aspects of the global payment structure (aside from the valuation of services) that commenters believe are noteworthy. Much of the discussion over the years has focused on whether global surgical packages are properly valued and whether they are needed at all. We encourage commenters to point out ways in which global surgical packages may continue to have a positive impact on health care delivery (such as their potential to support innovation). We also solicited suggestions on other ways that global surgical package payments could be modified (aside from changing their valuation) that could help improve accurate valuation or help address other concerns about the payments (such as the lack of transparency about what care is being provided as part of the package).

We also requested comment on additional information that we may not have considered or discussed above about proper valuation of the global packages, as well as any unintended impacts (or positive outcomes) that could result from changes to how we value global services. We are especially interested in public comment on any concerns about beneficiaries' access to care, continuity of care, cost sharing, or program integrity.

We received limited public comments on other payment structure changes, unintended consequences, and missing information. The following is a summary of the comments we received and our responses.

Comment: A few commenters opined on the consequences of unbundling global payments. A few of these commenters raised concerns that unbundling the packages would reduce payments to physicians or NPPs. A few expressed concerns that beneficiaries might not want to pay the coinsurance for standalone E/M visits (should global packages be unbundled) and might decline postoperative care.

Response: We agree that the payments to practitioners might change in circumstances where globals are revalued, although we do not believe there is yet enough information to determine the financial impact should proceduralists bill separately for postoperative care for some procedures. We will continue to consider the potential impact of coinsurance for globals and postoperative care for beneficiaries.

After consideration of the comments, we wish to thank the commenters for their input. As outlined in the proposed rule, this discussion has spanned over a decade, with participation from specialty societies, advocacy groups, program integrity agencies, and Congress. We had hoped through this comment solicitation to nudge discussion into new or under-explored lanes of inquiry that would help us better understand how global packages fit into the current health care landscape. We appreciate the engagement we did receive with our requests for information regarding current health care practices. Additionally, numerous interested parties, those who have been engaged with the discussion for many years, as well as some new voices, provided comment that reinforced or reiterated concerns that have emerged in prior discussions.

In this year's comment solicitation, we received a spectrum of perspectives on: whether the globals are misvalued; if misvalued, whether they are undervalued or overvalued; whether we should continue to value them through our current processes or develop a new methodology that better addresses the unique challenges posed by bundled payments; and whether globals should be revalued individually, in batches, or in their entirety. Looking at the totality of the comments and keeping in mind discussion from prior years, we have identified a few common themes on which many seem to agree. The matter of global valuation is complex. Global packages comprise a large number of codes, and their valuation has a significant impact on the PFS relative value scale. Accurately valuing the work and other inputs of the globals is critically important to ensure not only that the practitioners providing those services are paid accurately for the work performed, but that there is no inequitable impact on practitioners paid outside of 10- and 90-day global packages. The diversity of procedures paid under global packages may mean that blanket approaches to valuation or revaluation may not achieve the desired degree of accuracy. And, finally, while universally agreed-upon data strategies may prove elusive, good data analysis is a critical foundation on which to base any method for valuing these packages. We appreciate the public's engagement on this issue, and continue to welcome additional insights from interested parties as we consider appropriate next steps.

C. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.E. of this final rule, Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA) Resource-Based Relative Value Scale (RVS) Update Committee (RUC), MedPAC, and other interested parties. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by statute. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the

results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also considered information provided by other interested parties. We conducted a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/docs/Fee-for-Service-Payment/Physician default-source/reports/Mar06_Ch03.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE costs rise.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time-period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period (76 FR 73026, 73058 through 73059), other individuals and groups submit nominations for review of potentially misvalued codes as well. Individuals and groups may submit codes for review under the potentially misvalued codes initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox at *MedicarePhysicianFeeSchedule@cms.hhs.gov*, with the phrase ''Potentially Misvalued Codes'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes.'' Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior

reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the same CY 2012 PFS final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period (77 FR 68892, 68896 through 68897) we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes''). In the CY 2019 PFS proposed rule (73 FR 38589), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review of Work RVUs proposed rule (76 FR 32410, 32419), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time). We continue each year to consider and finalize a list of potentially misvalued codes that have or will be reviewed and revised as appropriate in future rulemaking.

3. CY 2023 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67548, 67606 through 67608), we modified this process whereby the public and interested parties may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In each year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

In each proposed rule, we seek nominations from the public and from interested parties of codes that they believe we should consider as potentially misvalued. We receive public nominations for potentially misvalued codes by February 10th and we display these nominations on our public website, where we include the submitter's name and their associated organization for full transparency. We sometimes receive submissions for specific, PE-related inputs for codes, and discuss these PE-related submissions, as necessary under the Determination of PE RVUs section of the rule. We summarize below this year's submissions under the potentially misvalued code initiative.

An interested party nominated the home-based physician visit codes: CPT code 99344 (*Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family*), CPT code 99345 (*Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent face-to-face with the patient and/or family*), CPT code 99349 (*Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family*), and CPT code 99350 (*Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting*

problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family) as potentially misvalued.

In their submission, the nominator expressed concern that there is no payment for transportation costs incurred when it is medically necessary for a physician to drive to the home of the patient for a face-to-face in-home E/M Visit, and that they are not compensated for opportunity loss they incur by seeing fewer patients because they spend time commuting to patients' homes, versus seeing more patients that come to their offices. The nominator also argued that Medicare does not compensate physicians for the work and time associated with assessing a patient's home environment, which provides insight into a patient's overall health and living conditions. The nominator collectively called these non-medical factors that can affect a patient's overall health the ''Social Determinants of Health'' (SDoH). The nominator requested that we increase the overall RVUs for CPT codes 99344, 99345, 99349, and 99350, by including the resources associated with: (1) the physician's transportation costs to patients' homes; (2) lost income opportunity for home versus in-office visits; and (3) in-home SDoH assessment work. The nominator estimated that the adjustments to RVUs to reflect transportation costs and opportunity costs would result in a Medicare payment that is 67 percent higher than the current Home-based E/M Visits payment rates, and that adjustments to account for the physician's SDoH assessment would add an additional 55 percent increase to the payment rates for Home-based E/M Visits. In total, the nominator suggests that if these resources were taken into account, the payment rates for Home-based E/M CPT codes would increase by what the nominator estimates as a 222 percent increase from their current amounts.

The nominator included references as evidence to support their claim that the home-based E/M CPT codes are potentially misvalued, such as the CMS ''Medicaid Non-Emergency Medical Transportation Booklet for Providers'' (April 2016) [6] [7] and a press release from the Better Medicare Alliance entitled, ''Report Shows Dramatic Increase in Medicare Advantage Activity to Address Social Determinants of Health, But Barriers Remain''.[8]

We noted that the nominator did not nominate the entire family of home-based E/M visit codes (please see Table 9 for a list of home-based E/M codes).

TABLE 9: Home-Based E/M CPT Codes for CY 2023

CPT	CPT Descriptor
Nominated Home Visits Codes:	
99344	New patient home visit, typically 1 hour
99345	New patient home visit, typically 75 minutes
99349	Established patient home visit, typically 40 minutes
99350	Established patient home visit, typically 1 hour
Home Visits Codes Not Nominated:	
99341	New patient home visit, typically 20 minutes
99342	New patient home visit, typically 30 minutes
99343	New patient home visit, typically 45 minutes
99347	Established patient home visit, typically 15 minutes
99348	Established patient home visit, typically 25 minutes

When we establish values for codes or consider whether codes are potentially misvalued under the PFS, we take into account the resources involved in furnishing the specific service as described by the CPT code. As such, historically, we do not take into account: (1) travel costs incurred by the physician or other practitioner; (2) potential opportunity costs to a physician or other practitioner when care is delivered in one setting versus another; or (3) the physician or other practitioner's work and time expended in performing activities that are outside the scope of the specific service as described by the CPT code. These are not considered to be resources involved in furnishing the service, and they are not included in establishing payment rates under the PFS in accordance with section 1848 of the Act, and, as such, do not provide justification for potential misvaluation of those payments. That said, in February 2021, the AMA CPT Editorial Panel deleted the family of domiciliary codes, CPT codes 99324 to 99340, and merged the services described by those codes into the existing family of home-based E/M visits, CPT codes 99341 to 99350 (a range of codes that includes CPT codes 99344, 99345, 99349, and 99350). In addition, the AMA RUC made recommendations regarding the values for these home-based E/M codes as discussed in section II.F. of the CY 2023 PFS proposed rule (87 FR 45999) and in section II.F. of this final rule. Since CMS had already received AMA RUC recommendations for these home-based E/M visit codes, we considered those recommendations and solicited additional public comments, recommendations, and independent analysis as supporting evidence from all interested parties regarding the valuations for the home-based E/M visits, including CPT codes 99344, 99345, 99349, and 99350. Because we discussed and solicited public comment on the valuation of these codes in the proposed rule, we stated that we were not considering these home-based E/M

[6] *https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/nemt-booklet.pdf.*

[7] *https://storage.aanp.org/www/documents/NP-Infographic.pdf.*

[8] *https://bettermedicarealliance.org/news/report-shows-dramatic-increase-in-medicare-advantage-activity-to-address-social-determinants-of-health-but-barriers-remain/#:~:text=Social%20determinants%20of%20health%20are,to%20the%20World%20Health%20Organization.*

visits as potentially misvalued for CY 2023.

An interested party has nominated the following cataract surgery codes, CPT codes 65820 (*Goniotomy—Incision to improve eye fluid flow*), 66174 (*Transluminal dilation of aqueous outflow canal; without retention of device or stent*), 66982 (*Complex Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification*), 66984 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification*)), 66989 (*Complex Extracapsular cataract removal w/IOL insertion, complex; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more),* and 66991 (*Extracapsular cataract removal w/IOL insertion; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more),* as well as the following retinal procedure codes, CPT codes 67015 (*Aspiration or release of vitreous, subretinal or choroidal fluid, pars plana approach (posterior sclerotomy)),* 67036 (*Vitrectomy, mechanical, pars plana approach),* 67039 (*Vitrectomy, mechanical, pars plana approach; with focal endolaser photocoagulation),* 67040 (*Vitrectomy, mechanical, pars plana approach; with endolaser panretinal photocoagulation*), 67041 (*Vitrectomy, mechanical, pars plana approach; with removal of preretinal cellular membrane (e.g., macular pucker)*), 67042 (*Vitrectomy, mechanical, pars plana approach; with removal of internal limiting membrane of retina (e.g., for repair of macular hole, diabetic macular edema), includes, if performed, intraocular tamponade (i.e., air, gas or silicone oil)*), 67043 (*Vitrectomy, mechanical, pars plana approach; with removal of subretinal membrane (e.g., choroidal neovascularization), includes, if performed, intraocular tamponade (i.e., air, gas or silicone oil) and laser photocoagulation*), 67108 (*Repair of retinal detachment; with vitrectomy, any method, including, when performed, air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique*), and 67113 (*Repair of complex retinal detachment (e.g., proliferative vitreoretinopathy, stage C–1 or greater, diabetic traction retinal detachment, retinopathy of prematurity, retinal tear of greater than 90 degrees), with vitrectomy and membrane peeling, including, when performed, air, gas, or silicone oil tamponade, cryotherapy, endolaser photocoagulation, drainage of subretinal fluid, scleral buckling, and/or removal of lens*), as potentially misvalued because there is currently no established non-facility payment rate for these global 090-day surgical procedures. These codes are complex surgical eye procedures, and they require dedicated spaces, similar to facility-based spaces that are not typically found in an ophthalmologist's office—such as a well-lighted and sterile surgical theater; specific eye surgery equipment; and, possibly, clinical staff and other medical personnel trained to assist in these surgeries and the patient's immediate post-surgery recovery, including anesthesia services. In the past, with concerns for patient safety and given the intricate and delicate nature of these surgeries, we understood that these procedures would only be performed in a well-equipped and fully staffed medical facility. For Medicare Part B, payment for these services is only made for procedures furnished in the facility settings, but this nominator suggests that these cataract and retinal procedures can be properly performed in the non-facility office, safely, effectively, and perhaps more conveniently for patients and physicians; and thus requests that we should establish non-facility RVUs under the PFS to recognize the additional resources that would be expended in the non-facility setting.

The nominator has included a list of practice expense (PE) items involved in furnishing these services in the non-facility setting to help us to consider establishing non-facility values for these codes. They include the possible number and types of clinical staff and their work time in minutes as well as a list of various equipment and supplies typically needed to furnish the services described by the nominated codes.

The nominator also noted that there is projected backlog for these cataract and retinal services that may have been building up due to the COVID–19 restrictions from the past 2 years. We solicited comment on the merits of continuing to value these codes only in the facility setting, as opposed to also establishing non-facility values for these cataract and retinal surgery codes. We also solicited comment on any appropriate safety considerations for these codes in the non-facility setting, and whether these codes are potentially misvalued. We noted that in last year's CY 2022 PFS final rule with comment (86 FR 65096 through 65097), we did review CPT codes 66982, 66984, 66987, 66988, 66989, 66991, and 0671T (Cataract Removal *with* Drainage Device Insertion) and did not establish non-facility values for those services, but we did note a potential rank order anomaly when considering minimally invasive glaucoma surgeries (MIGS) and cataract surgeries together, and suggested that the AMA RUC should consider re-surveying all of the codes in this family.

An interested party nominated add-on CPT code 20931 (*Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)*) as a potentially misvalued service with respect to the physician's labor for spinal surgeries involving the use of biomechanical synthetic cage devices versus the use of structural allograft bone as it relates to a set of CPT codes related to anterior cervical discectomy and fusion (ACDF). Ordinarily, interested parties nominate a primary service code as potentially misvalued, or a primary service code and its related add-on codes, but not an add-on code alone. The valuation of an add-on code is typically developed with reference to some portion of the work (or other resource inputs) involved in furnishing the primary service code. For example, the AMA CPT 2022 Professional Edition, page 147, states ''Use code 20931 in conjunction with codes 22319, 22532–22533, 22548–22558, 22590–22612, 22630, 22633, 22634, 22800–22812''. The primary spinal surgery codes and the add-on CPT code 20931 have not been recently reconsidered or reviewed by the AMA RUC or CMS, and no new or additional information has been included with this nomination to persuade CMS that CPT code 20931 is individually potentially misvalued. This nomination of an add-on code as potentially misvalued is similar to the nomination we discussed in the CY 2022 PFS proposed rule (86 FR 65044) of CPT code 22551 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2*) and the accompanying add-on codes.

The nominator refers to two different methods of vertebral fusion: one using biomechanical synthetic cage devices, the other using structural allograft bone; and describes a typical vertebral fusion case that uses three units of one of these products. Both of these methods of vertebral fusion are described by CPT

code 22551 (includes a 90-day global period), which has a work RVU of 25.00. Both methods of vertebral fusion also involve two units of CPT code 22552 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure)*), which have a total work RVU of 13.00 (6.50 × 2), and 1 unit of CPT code 22846 (*Anterior instrumentation; 4 to 7 vertebral segments (List separately in addition to code for primary procedure)*), which has a work RVU of 12.40. The vertebral fusion method employing three synthetic cage devices with plate would involve three units of CPT code 22853 (*Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)*) for a total work RVU of 12.75 (4.25 × 3), and one unit of CPT code 20930 (*Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)*) with a work RVU of 0.00 (because Medicare considers this code to be bundled into codes for other services). The nominator states that the typical vertebral fusion employing three synthetic cage devices with plate would total to 63.15 work RVUs.

In contrast, the nominator asserts that the vertebral fusion method employing structural allograft bones with plate involves the same set of services and codes (that is, one unit of CPT code 22551, two units of CPT code 22552, and one unit of CPT code 22846), but the structural allograft bone method includes CPT code 20931 (*Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)*), with a work RVU of 1.81, instead of CPT codes 22853 and 20930, for a total work RVU of 52.21. The nominator suggests that this difference in total work RVUs for the two methods of vertebral fusion, 63.15 versus 52.21, is evidence that add-on CPT code 20931 is potentially misvalued; however, we do not agree with this nominator's method of aggregating and comparing sums of work RVUs for groups of services that may be furnished together as being potentially misvalued, nor consider CPT code 20931 as the source of misvaluation within this grouping.

We understand that the nominator believes there should be an equivalent total sum payment for all services involved in vertebral fusion surgeries using either method, and that there should not be a potential incentive for physicians to prefer the method that uses synthetic cage devices because of the higher available payment amount. The nominator asserts that the total sum payment for this kind of spinal surgery using the structural allograft bone method is undervalued as compared to the total sum payment for this kind of spinal surgery using the synthetic cage method.

We note that CPT code 22853, which the commenter associates with the synthetic cage device method of vertebral fusion, is a 45-minute ZZZ-code (indicating an add-on code) with an IWPUT (intra-service work (RVU) per unit of time) of 0.0944, whereas CPT code 20931, which the commenter associates with the allograph method of vertebral fusion, is a 20-minute ZZZ-code with an IWPUT of 0.0905. Given the much longer intra-service time and greater IWPUT for CPT code 22853 than for CPT code 20931, the allograph method of vertebral fusion would be expected to have a lower total sum of work RVUs.

The nominator's description of why and how each vertebral fusion method is potentially misvalued when compared to the other does not present a situation that fits within our process for identifying individual services that are potentially misvalued using certain criteria, as described in the beginning of this section. Our determination that one or more codes are potentially misvalued generally revolves around the specific RVUs assigned to individual codes, or with the inter-code relativity between the RVUs assigned to several individual codes found within a family of codes with hierarchical relationships. We generally do not examine the summed differences in total RVUs (as is the case presented here), based on billing patterns for a combination of codes representing differing physician work for different methods of performing a service, and then comparing the total RVUs of each method as evidence of the potential misvaluation of codes. We do not believe that the nominator has provided sufficient evidence to demonstrate that CPT code 20931 itself is misvalued, and therefore, we are not inclined to propose this code as potentially misvalued; however, we solicited additional comment and any independent analysis and studies (see the supporting documentation options listed above under ''CY 2023 Identification and Review of Potentially Misvalued Services,'' particularly in regard to any changes in the resources to providing a service) as supporting evidence from commenters in agreement or disagreement with this nomination.

See Table 10 for the listing of nominated potentially misvalued codes.

TABLE 10: Interested Parties' Nominations of CPT Codes as Potentially Misvalued for CY 2023

CPT	CPT Descriptor
Home Visits codes:	
99344	New patient home visit, typically 1 hour
99345	New patient home visit, typically 75 minutes
99349	Established patient home visit, typically 40 minutes
99350	Established patient home visit, typically 1 hour
Cataract Surgery codes:	
65820	Relieve inner eye pressure
66174	Translum dil eye canal
66982	Xcapsl ctrc rmvl cplx wo ecp
66984	Xcapsl ctrc rmvl w/o ecp
66989	Xcpsl ctrc rmvl cplx insj 1+
66991	Xcapsl ctrc rmvl insj 1+
Retinal Procedure codes:	
67015	Release of eye fluid
67036	Removal of inner eye fluid
67039	Laser treatment of retina
67040	Laser treatment of retina
67041	Vit for macular pucker
67042	Vit for macular hole
67043	Vit for membrane dissect
67108	Repair detached retina
67113	Repair retinal detach cplx
Spinal Surgery code:	
20931	Allograft, structural, for spine surgery only (add-on code)

We received public comments on our discussion of public nominations for potentially misvalued codes and decision not to propose them as potentially misvalued. The following is a summary of the comments we received and our responses.

We received a number of public comments on the nominated home-based E/M visit CPT codes 99344, 99345, 99349, and 99350.

Comment: Commenters were disappointed, stating that CMS did not take into account the inclusion of the nominator's request for consideration for: (1) travel costs incurred by the physician or other practitioner; (2) potential opportunity costs to a physician or other practitioner when care is delivered in the patient's home versus in the office or at a facility; or (3) the physician or other practitioner's work and time expended assessing a patient's home environment and/or ''Social Determinants of Health'' (SDoH) assessments. Commenters explained that the typical home-bound patient, who requires a physician home visit, is comparatively more frail, with multiple chronic conditions. Some commenters suggested add-on codes, similar to the codes for at-home COVID–19 Vaccinations, for physician transportation costs to the patient's home.

Response: We appreciate the feedback from commenters and encourage further discussion as we gain more experience with the new codes. As discussed in our proposed rule, the costs identified by commenters are not considered to be specific work, practice expense, or malpractice expense resource inputs that are taken into account in valuation of individual services under the PFS, so they are not included in establishing payment rates under the PFS in accordance with section 1848 of the Act. As such, these costs do not provide justification for potential misvaluation of the identified codes. We also noted in the CY 2023 PFS proposed rule (87 FR 45883) that the AMA RUC made recommendations regarding the values for these home-based E/M visit codes. Since CMS had already received AMA RUC recommendations for these home-based E/M visit codes for this year's proposed rule, we referred readers to the discussion and solicitation of public comments on those recommendations in the proposed rule. We solicited additional public comments, recommendations, and independent analysis as supporting evidence from all interested parties regarding the valuations for the home-based E/M visits, including CPT codes 99344, 99345, 99349, and 99350. We refer readers to section II.F. of this final rule for a summary and our responses to those comments. With regard to the comments requesting additional coding, we appreciate commenters' suggestions, and, as we gain information from utilization of the newly-reviewed codes and receive additional feedback from interested parties, we may consider changes in future rulemaking.

Comment: One commenter stated that his Home Visit PEs are not lower than those of an office practice, but did not offer any code-level details to support this statement.

Response: We appreciate the perspective of interested parties, but we would need code-level PE details to evaluate potential code valuation issues.

We received numerous comments on the Cataract and Retinal Surgery codes which were nominated as potentially misvalued with a request to establish nonfacility payment rates for these complicated 090-day global surgical procedures.

Comment: Several commenters requested that CMS revise the current work RVU for CPT code 66174 (*Transluminal dilation of aqueous outflow canal; without retention of device or stent*) and instead use the

higher AMA RUC-recommended work RVU value or, short of that, transition the valuation we established in the CY 2022 PFS final rule over 3 years.

Response: We thank commenters for this comment. CPT code 66174 was reviewed and finalized in last year's rule (85 FR 65095), and we will not consider this code as potentially misvalued for CY 2023. We did not identify or propose CPT code 66174 as potentially misvalued in the proposed rule. As such, this comment is outside the scope of the proposed rule.

Comment: Many commenters recounted the evolution of these Cataract and Retinal Surgery codes—once exclusively performed in hospital operating theaters, then performed in ASCs, and now perhaps maturing into the next phase of eye care and Office-Based Surgeries (OBS). Commenters were mainly in favor of establishing payment amounts for these services in the non-facility office setting, which would recognize the additional PE resources involved in furnishing the services in those settings. Commenters also stated that there are significant advantages to be gained when these cataract and retinal surgery services are furnished in non-facility office settings. OBS may offer faster scheduling and coordinating with the surgeon, patient, and patient's family caretaker, since they bypass additional schedule coordination, and avoid potential staffing or availability issues with the hospital or ASC operating room. These commenters suggested that scheduling activities may be more efficient and flexible in the OBS setting, leading to fewer and shorter delays in delivering these Cataract and Retinal Surgeries to alleviate the patient's urgent eye problem (especially during recent COVID–19-related restrictions). The commenters also suggested that office-based surgical staff are also more likely to be familiar to the patient than a hospital operating room or ASC staff. One commenter offered that organizations, such as the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), may offer accreditation for practitioners interested in furnishing OBS for these services, to prove they can demonstrate they have adequate equipment, adequate sterility, adequate backup power and lights, adequate clinical surgery personnel, and adequate emergency personnel, should there be a need for them, compared to hospital operating rooms or ASCs, possibly maintaining certifications with periodic re-inspections.

Some Hospital/ASC-based commenters noted that, after decades of ophthalmologist experience with these Cataract and Retinal Surgery codes, they had a number of concerns about these services shifting toward office-based surgeries compared with Hospital/ASC settings and whether OBS can adequately address these concerns, including: (1) Sterility controls equal or better than a hospital operating room or a dedicated ASC operating theater; (2) Anesthesia for the OBS that is different in the office where valium oral sedation may be used and the patient being monitored by the physician eye surgeon, rather than in an O.R. with general sedation via IV administered and monitored by an anesthesiologist; (3) Equipment quality and maintenance is a concern and in the smaller typical office setting, there may not be the backups and redundancies that may be found in the larger facility settings, with automatic emergency power switchovers that may not be installed for the OBS; (4) Patient complications being detected in the pre-screening phase, possible complications occurring during the surgical procedure phase, and possible complications during the post-procedure phase, are concerns for the OBS, which may not have the full facility resources to address emergency situations arising from the office based surgery; (5) Staff for OBS are likely to be well familiar with eye surgeries and the patients themselves, but a general O.R. or ASC staff might be more experienced in responding to a wider range of surgical related complications; (6) The intricate, delicate, and complicated surgical procedures performed by varying experienced eye surgeons remains a concern when these procedures are performed outside of a full facility operating theater; (7) There is considered by some commenters to be a paucity of independent, high-quality, peer-reviewed clinical data supporting the safety or feasibility of retina surgery performed in an office setting, nor do they believe that there is any widespread demand by retina specialists or patients for this OBS option.

Response: We appreciate commenters' perspectives regarding their experience and concerns for Cataract and Retinal Surgeries being furnished as OBS. As we continue to consider how and where these services are furnished, and whether they are typically furnished in different settings, information such as the comments provided by these and other commenters are helpful. Based upon commenters' feedback, we have concerns about these services being furnished in non-facility settings. It is also unclear whether these services are routinely being furnished outside of facility settings. CMS will continue to evaluate whether these services are being furnished in non-facility settings and will consider establishing non-facility values for these services at that time.

Comment: The AMA RUC commented that it defers to the ophthalmology and retinal specialty societies to determine whether these services could be safely performed in the non-facility setting; the specialty societies recommend against CMS moving forward with making these services payable as OBS, citing many of the same commenters' concerns listed earlier in this section.

Response: We appreciate the AMA RUC's response to this issue, explaining that they defer to the specialty societies' position on this issue.

After consideration of public comments, we will continue to gather information concerning Cataract and Retinal Surgeries in the non-facility office settings and their implications to Medicare payment for future rulemaking.

We received a few public comments on the nominated CPT code 20931 (*Allograft, structural, for spine surgery only (add-on code)*) and other codes related to anterior cervical discectomy and fusion (ACDF).

Comment: One commenter agreed with the nominator that CPT code 20931 is misvalued when compared to CPT code 22853 (*Insertion of cage or mesh device to spine bone and disc space during spine fusion (add-on code)*) and other codes related to anterior cervical discectomy and fusion (ACDF), where the higher payment for CPT code 22853 inappropriately incentivizes surgeons to insert the synthetic cage spacer over the bone allograft. However, one commenter stated that there is no evidence that CPT code 20931 is misvalued, and that the valuation of CPT code 20931 should not be equivalent to CPT code 22853.

Response: We thank these commenters for their feedback. As this nomination is almost identical to a grouping of related codes for ACDF that had been presented in the CY 2022 PFS proposed rule (86 FR 65044), under CPT code 22551 as misvalued, and as it was discussed at that time and reviewed again in this rule, we do not believe that the nominator has provided sufficient evidence to demonstrate that CPT code 20931 is misvalued nor that this code's payment should be made equivalent to CPT code 22853. As stated earlier, our determination that one or more codes are potentially misvalued generally revolves around the specific RVUs assigned to individual codes, or with the inter-code relativity between the

RVUs assigned to several individual codes found within a family of codes with hierarchical relationships. We generally do not examine the summed differences in total RVUs (as is the case presented here), based on billing patterns for a combination of codes representing differing physician work for different methods of performing a service, and then comparing the total RVUs of each method as evidence of the potential misvaluation of codes. We do not believe that the nominator or other interested parties have provided sufficient evidence to demonstrate that CPT code 20931 itself is misvalued, and therefore, we are not inclined to propose (or adopt) this code as potentially misvalued.

After consideration of public comments, we are finalizing our proposal not to adopt any of the nominated codes as potentially misvalued codes. We encourage commenters who wish to nominate codes as potentially misvalued to consider the types of supporting documentation listed in the beginning of this section, as that information is important for us to consider in our process for reviewing nominations of potentially misvalued codes.

D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. See further details and full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006) and CY 2021 PFS final rule (85 FR 84502) and in 42 CFR 410.78 and 414.65.

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

a. Changes to the Medicare Telehealth Services List

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare Telehealth Services List in accordance with section 1834(m)(4)(F)(ii) of the Act (§ 410.78(f)). This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us and assigned to categories established through notice and comment rulemaking. Specifically, we assign any submitted request to add to the Medicare Telehealth Services List to one of the following two categories:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare Telehealth Services List. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to those on the current Medicare Telehealth Services List. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits. Some examples of other clinical benefits that we consider include the following:
  - Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
  - Treatment option for a patient population without access to clinically appropriate in-person treatment options.
  - Reduced rate of complications.
  - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
  - Decreased number of future hospitalizations or physician visits.
  - More rapid beneficial resolution of the disease process treatment.
  - Decreased pain, bleeding, or other quantifiable symptom.
  - Reduced recovery time.

In the CY 2021 PFS final rule (85 FR 84507), we created a third category of criteria for adding services to the Medicare Telehealth Services List on a temporary basis following the end of the PHE for the COVID–19 pandemic: Category 3. This new category describes services that were added to the Medicare Telehealth Services List during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria. Services added on a temporary, Category 3 basis will ultimately need to meet the criteria under Category 1 or 2 in order to be permanently added to the Medicare Telehealth Services List. To add specific services on a Category 3 basis, we conducted a clinical assessment to identify those services for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth. We considered the following factors:

++ Whether, outside of the circumstances of the PHE for COVID–19, there are concerns for patient safety if the service is furnished as a telehealth service.

++ Whether, outside of the circumstances of the PHE for COVID–19, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care.

++ Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio-video telecommunications technology.

In the CY 2021 PFS final rule (85 FR 84507), we also temporarily added several services to the Medicare Telehealth Services List using the Category 3 criterion described above. We assessed codes that were temporarily available on the list for the duration of the PHE to determine their appropriateness for inclusion on the Medicare Telehealth Services List on a Category 3 basis. We have reassessed the services that are temporarily available via telehealth for the PHE, based on both information provided by interested parties and our own internal review. We have assessed whether or not these services can, outside of the circumstances of the PHE, be furnished using the full scope of service elements via two-way, audio-video communication technology, without jeopardizing patient safety or quality of care, and we now believe that there are additional services that would be appropriate for addition to the Medicare Telehealth Services List on a Category 3 basis that we did not identify in the CY 2021 rulemaking. In the proposed rule, we proposed to add these additional services to the Medicare Telehealth Services List on a Category 3 basis, as further discussed below.

The Medicare Telehealth Services List, including the additions described later in this section, is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

Beginning in CY 2019, we stated that for CY 2019 and onward, we intend to accept requests through February 10, consistent with the deadline for our receipt of code valuation recommendations from the RUC (83 FR 59491). For CY 2023, requests to add services to the Medicare Telehealth Services List must have been submitted and received by February 10, 2022. Each request to add a service to the Medicare Telehealth Services List must have included any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as the vehicle to make changes to the Medicare Telehealth Services List, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request in the future to add services to the Medicare Telehealth Services List, including where to submit these requests, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

b. Requests To Add Services to the Medicare Telehealth Services List for CY 2023

Under our current policy, we add services to the Medicare Telehealth Services List on a Category 1 basis when we determine that they are similar to services on the existing Medicare Telehealth Services List for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the Category 1 criterion not only streamlines our review process for publicly requested services that fall into this category, but also expedites our ability to identify codes for the Medicare Telehealth Services List that resemble those services already on the Medicare Telehealth Services List. We add services on a Category 2 basis when the service does not fall within Category 1, and based upon our assessment of whether the services are accurately described by the corresponding code when delivered via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. We add services on a temporary Category 3 basis when the services were temporarily included on the Medicare Telehealth Services List during the PHE, and we find that there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria.

We received several requests to permanently add various services to the Medicare Telehealth Services List effective for CY 2023. We found that none of the requests we received by the February 10th submission deadline met our Category 1 or Category 2 criteria for permanent addition to the Medicare Telehealth Services List. We also assessed the appropriateness of adding these services to the Medicare Telehealth Services List on a Category 3 basis instead.

We did not propose changes to the length of time the services that we temporarily included on a Category 3 basis will remain on the Medicare Telehealth Services List; the services we temporarily included on the Medicare Telehealth Services List on a Category 3 basis will continue to be included through the end of CY 2023. In the CY 2023 PFS proposed rule, we noted that in the event that the PHE extends well into CY 2023, we may consider revising this policy.

We proposed to add some services to the Medicare Telehealth Services List on a Category 3 basis through the end of 2023, some of which we had not previously added to the Medicare Telehealth List during the PHE, but have been added on a subregulatory basis as provided in § 410.78(f) of our regulations. For some of these services, we received information from interested parties suggesting potential clinical benefit. For others, we continue to believe there is sufficient evidence of potential clinical benefit to warrant allowing additional time for interested parties to gather data to support their possible inclusion on the Medicare Telehealth Services List on a Category 1 or 2 basis. The Medicare Telehealth Services List requests for CY 2023 are listed in Table 11.

Additionally, the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022) amended section 1834(m) of the Act to extend a number of flexibilities that are in place during the PHE for COVID–19 for 151 days after the end of the PHE. To align the availability of these services with those flexibilities extended under the Act, we proposed to continue to allow certain telehealth services that would otherwise not be available via telehealth after the expiration of the PHE to remain on the Medicare Telehealth Services List for 151 days after the expiration of the PHE.

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TABLE 11: Services Requested for Addition to the Medicare Telehealth Services List for CY 2023

HCPCS	Long Descriptor	Basis
	Code Family	
	Lactation classes	
S9443	Lactation classes, non-physician provider, per session	
	Telephone E/M	
99441	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	3
99442	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion	3
99443	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion	3
	Therapy	
90901	Biofeedback training by any modality	1
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility	1
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities	1
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)	1
97150	Therapeutic procedure(s), group (2 or more individuals)	1
97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.	1
97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.	1
97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.	1
97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.	1
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes	1

HCPCS	Long Descriptor	Basis
97535	Self-care/home management training (e.g., activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes	1
97537	Community/work reintegration training (e.g., shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes	1
97542	Wheelchair management (e.g., assessment, fitting, training), each 15 minutes	1
97750	Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes	1
97755	Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes	1
97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes	1
98960	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient	1
98961	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 2-4 patients	1
98962	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients	1
Gastrointestinal tract imaging		
91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report	3
Ambulatory continuous glucose monitoring		
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report	N/A
Electronic analysis of implanted neurostimulator pulse generator/transmitter		
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	1
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	1
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming	3
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional	3
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)	3
Adaptive behavior treatment and Behavior identification assessment		

HCPCS	Long Descriptor	Basis
97151	Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan	2
97152	Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes	2
97153	Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes	2
97154	Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes	2
97155	Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes	2
97156	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes	2
97157	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes	2
97158	Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes	2
0362T	Behavior identification supporting assessment, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.	2
0373T	Adaptive behavior treatment with protocol modification, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.	2

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We remind interested parties that the criterion for adding services to the Medicare Telehealth Services List under Category 1 is that the requested services are similar to professional consultations, office visits, and/or office psychiatry services that are currently on the Medicare Telehealth Services List, and that the criterion for adding services under Category 2 is that there is evidence of clinical benefit if provided as telehealth. As explained below, we find that none of the requested services listed in Table 11 met the Category 1 or 2 criteria.

We received a request to permanently add CPT code S9443 (*Lactation classes, non-physician provider, per session*) to the Medicare Telehealth Services List. This service has a status code of ''I,'' which means that it is not valid for Medicare billing purposes. We understand that this is a temporary code established by a private payor for private payor use, and thus, it is not valid for nor payable by Medicare. As such, this code is not separately billable under the PFS. We generally do not add services to the Medicare Telehealth Services List unless they are separately billable under the PFS. Outside of the circumstances of the PHE, the Medicare Telehealth Services List only includes services that are covered if they are furnished without the use of telecommunication technology in-person. Because CPT code S9443 is not billable under the PFS when furnished in-person, we do not believe it would be appropriate to allow the service to be billed separately when furnished as a Medicare telehealth service. As noted in the CY 2018 PFS final rule (82 FR 53011), if a service does not describe a service typically furnished in-person, it would not be considered a telehealth service under the applicable provisions of the statute. We did not propose to add CPT code S9443 to the Medicare Telehealth Services List.

Comment: A commenter requested that this code (CPT code S9443) be added on a Category 3 basis, citing financial pressures and staff shortages, which are affecting labor and delivery units.

Response: We thank the commenter for this comment, but as noted in the proposed rule, this code is not separately billable under the PFS when furnished in-person, so we do not believe that it should be considered a telehealth service within the meaning of the statute. We continue to believe it would be inappropriate to allow CPT code S9443 to be billed separately when furnished as a Medicare telehealth service, and we are finalizing our proposal not to add CPT code S9443 to the Medicare Telehealth Services List.

(1) Therapy Services

We received requests to add Therapy Procedures: CPT codes 97110, 97112, 97116, 97150, and 97530; Physical Therapy Evaluations: CPT codes 97161–97164; Therapy Personal Care services: CPT codes 97535, 97537, and 97542; and Therapy Tests and Measurements services: CPT codes 97750, 97755, and 97763, to the Medicare Telehealth Services List on a Category 1 basis.

In the CY 2022 PFS final rule (86 FR 65051), we determined that these services did not meet the Category 1 criteria for addition to the Medicare Telehealth Services List because they involve direct observation and/or physical contact between the practitioner and the patient and, in many instances, are therapeutic in

nature, and that they did not meet Category 2 criteria, because we thought that the request did not provide sufficient detail to determine whether all of the necessary elements of the service could be furnished remotely. We continue to believe this is the case. We still do not have sufficient information to determine whether these services meet the Category 2 criteria. However, we noted that some of these codes, including codes 97110, 97112, 97116, 97150, 97530, 97161–97164, 97535, 97542, 97750, and 97755 have been added to the list on a temporary basis for the duration of the PHE.

In assessing the evidence that was supplied by interested parties in support of adding these services to the Medicare Telehealth Services List on a Category 2 basis, we concluded that there was not sufficient information to determine whether all of the necessary elements of these services could be furnished remotely. Information regarding safety, appropriateness, and that indicates that all elements of a given CPT code can be furnished via telehealth is still needed to assess whether these services meet the Category 2 criteria. However, we also believe that the therapy services that are currently on the Medicare Telehealth Services List on a temporary basis for the PHE (including CPT codes 97150, 97530, and 97542), but are not currently included on a Category 3 basis, may continue to be furnished safely via two-way, audio-video communication technology outside of the circumstances of the PHE.

Therefore, we proposed that CPT codes 97150, 97530, and 97542 (the set of therapy services that are currently on the Medicare Telehealth Services List on a temporary basis for the PHE) be added to the Medicare Telehealth Services List through the end of CY 2023 on a temporary, Category 3 basis, to allow time to gather additional data that could support their possible inclusion on the list on a permanent basis. CPT codes 97110, 97112, 97116, 97161–97168, 97535, 97750, and 97755 will continue to be available on the Medicare Telehealth Services List on a Category 3 basis. We anticipate that keeping these services on the Medicare Telehealth Services List on a Category 3 basis, as proposed, through the end of CY 2023 would preserve access to care and promote health equity, and based on information provided by interested parties and internal review, we believe that they may safely be furnished as telehealth outside of the circumstances of the PHE through the end of CY 2023. However, we remind readers that the practitioners who primarily furnish these services, physical therapists, are not, outside the circumstances of the PHE (and the 151-day period following the expiration of the PHE), authorized to furnish Medicare telehealth services. We noted that, if the PHE and the 151-day period following the expiration of the PHE both end in CY 2023, the pre-PHE rules will take effect, and these services could no longer be furnished by therapists as Medicare telehealth services.

Certain other requested therapy services, namely CPT codes 97537, 97763, 90901, and 98960–98962 were not on the Medicare Telehealth Services List prior to June 16, 2022; however, we added these services to the Medicare Telehealth Services List on a temporary basis during the PHE, in accordance with § 410.78(f). As explained below in section II.D.1.d. of this final rule, services included on the Medicare Telehealth Services List on a temporary basis during the PHE that have not been added to the list on a Category 3 basis will remain on the list for 151 days following the end of the PHE. Furthermore, we proposed to add CPT codes 97537, 97763, 90901, and 98960–98962 to the Medicare Telehealth Services List on a Category 3 basis through the end of CY 2023. Our clinical analyses of these services indicate that they can be furnished in full using two-way, audio and video technology during the circumstances of the PHE, and information provided by requestors indicates that there may be clinical benefit; however, there is not yet sufficient evidence available to consider the services for permanent addition to the Medicare Telehealth Services List under the Category 1 or Category 2 criteria. Including these services on the Medicare Telehealth Services List during the PHE and through CY 2023 will allow additional time for the development of evidence for CMS to consider when evaluating these services for potential permanent addition to the Medicare Telehealth Services List on a Category 1 or 2 basis. We continue to encourage commenters to supply additional information in support of adding these services to the Medicare Telehealth Services List on a permanent basis, including information regarding the safety and appropriateness of furnishing these services via telehealth.

Comment: Several commenters supported our addition of the listed therapy services to the Medicare Telehealth Services List on a Category 3 basis. However, commenters stated that many of these codes should be added permanently; commenters specifically stated that therapy services, including CPT codes 97110, 97112, 97116, 97150, 97161–97164, 97530, 97535, 97537, 97542, 97750, 97755, 97763, 90901, 98960, 98961, and 98962 should be added permanently, stating that these codes have been used successfully to provide telehealth services throughout the PHE and have shown that the same quality of care can be given with equal or higher levels of patient satisfaction as in-person visits. According to these commenters, the PHE has given ample data to support that, when used appropriately, telehealth can have a positive effect on outcomes for patients who are restricted from a full course of in-person therapy visits, which they claim is at a lower cost of care, and the inclusion of these therapy service codes on the Medicare Telehealth Services List on a Category 1 or Category 2 basis would preserve access to these services beyond the temporary extension and ease administrative burden should Congress act in the future to make rehabilitation services delivered via telehealth permanent.

Response: We note that all of the above-mentioned therapy services are either currently on the Medicare Telehealth Services List on a Category 3 basis, or we have proposed to add them on a Category 3 basis for CY 2023, to continue to gather data with regard to likely clinical benefit when furnished via telehealth outside of the circumstances of the PHE. We continue to believe that the process as discussed in the CY 2021 PFS final rule (85 FR 84506 through 84509), whereby we created the Category 3 basis for adding to or deleting services from the Medicare Telehealth Services List is the appropriate means of potentially adding services permanently for those services that were temporarily added under the circumstances of the PHE, as this process allows for the collection and evaluation of data that could potentially support permanent inclusion following the 151-day period after the end of the PHE. We believe our proposal, consistent with the amendments made by provisions of the CAA, 2022, to extend the period that these services will be available on the Medicare Telehealth Services List temporarily for the PHE by 151 days following the end of the PHE will further enhance the opportunity for the collection of information on the experiences of clinicians who are furnishing telehealth services during the PHE for COVID–19. This will also help us to determine which services may ultimately be eligible for permanent addition under Category 1 or Category 2 criteria, and we encourage interested parties to use this

extended time period to gather data on use of services, that is more than statements of support and more than subjective attestations of clinical benefit, to support their potential addition in future rulemaking.

Comment: Commenters requested clarification on whether CPT codes for Occupational Therapy (97165, 97166, 97167, and 97168) and Speech Therapy (92522 and 92523) were included in the list of Category 3 codes for CY 2023, and should be added on a Category 3 basis.

Response: We clarify that these codes (CPT codes 97165–97168 and 92521–92524) are currently included on the Medicare Telehealth Services List available on a Category 3 basis.

After consideration of public comments, we are finalizing our proposed addition of CPT codes 90901, 97150, 97530, 97537, 97542, 97763, and 98960–98962 to the Medicare Telehealth Services List on a Category 3 basis.

(2) Telephone E/M Services

We have also received requests to temporarily add Telephone E/M visit codes, CPT codes 99441, 99442, and 99443 to the Medicare Telehealth Services List on a Category 3 basis. In the March 31, 2020 interim final rule with comment period (IFC), we established separate payment for audio-only telephone E/M services (85 FR 19264 through 19266) for the duration of the PHE for the COVID–19 pandemic. Although these services were previously considered non-covered under the PFS, in the context of the PHE for COVID–19 and with the goal of reducing exposure risks associated with COVID–19 (especially in situations when two-way, audio and video technology is not available to furnish a Medicare telehealth service), we believed there were circumstances where prolonged, audio-only communication between the practitioner and the patient could be clinically appropriate, yet not fully replace a face-to-face visit. In the May 8, 2020 COVID–19 IFC, we noted that interested parties had informed us that use of audio-only services was more prevalent than we had previously considered, especially because many beneficiaries were not using video-enabled communication technology from their homes. In other words, there were many cases where practitioners who would ordinarily furnish audio-video telehealth or in-person visits to evaluate and manage patients' medical concerns were instead using audio-only interactions to manage more complex care (85 FR 27589 through 27590). While we had previously acknowledged the likelihood that, under the circumstances of the PHE for COVID–19, more time would be spent interacting with the patient via audio-only technology, we stated that the intensity of furnishing an audio-only visit to a beneficiary during the unique circumstances of the PHE for COVID–19 was not accurately captured by the valuation of these services that we established in the March 31, 2020 IFC (85 FR 27590). This will be particularly true to the extent that these audio-only services are serving as a substitute for office/outpatient (O/O) Medicare telehealth visits for beneficiaries not using video-enabled telecommunications technology, which is contrary to the situation we anticipated when establishing separate payment for them in the March 31, 2020 IFC. In the May 8, 2020 COVID–19 IFC, we stated that, given our understanding that these audio-only services were being furnished primarily as a replacement for care that would otherwise be reported as an in-person or telehealth visit using the O/O E/M codes, we established new RVUs for the telephone E/M services based on crosswalks to the most analogous O/O E/M codes, based on the time requirements for the telephone codes and the times assumed for valuation for purposes of the O/O E/M codes. Specifically, we crosswalked the levels 2–4 O/O E/Ms for established patients, as described by CPT codes 99212, 99213, and 99214, to CPT codes 99441, 99442, and 99443, respectively. Additionally, we stated that, given our understanding that these audio-only services were being furnished as substitutes for O/O E/M services, we recognized that they should be considered as telehealth services, and added them to the Medicare Telehealth Services List for the duration of the PHE for COVID–19 (85 FR 27590).

In the CY 2022 PFS final rule (86 FR 65055), in response to requests that these codes be added to the Medicare Telehealth Services List on a Category 3 basis, we stated that we were finalizing a change to the definition of ''telecommunications system'' to allow telehealth services for the diagnosis, evaluation, and treatment of mental health conditions to be furnished through audio-only technology in certain circumstances after the end of the PHE. For example, the O/O E/M codes are on the Medicare Telehealth Services List permanently and when used to describe care for mental health conditions, will be reportable when furnished via audio-only technology to patients in their homes. Since audio-only telecommunications technology can be used to furnish mental health telehealth services to patients in their homes, the addition of these codes to the Medicare Telehealth Services List is unnecessary for mental health telehealth services. For telehealth services other than mental health care, we stated that we believe that two-way, audio-video communications technology is the appropriate standard that will apply for telehealth services after the PHE ends. Further, we noted that section 1834(m)(2)(A) of the Act requires that payment to a distant site physician or practitioner that furnishes Medicare telehealth services to an eligible telehealth individual be equal to the amount that would have been paid under Medicare if such physician or practitioner had furnished the service without a telecommunications system. We believe that the statute requires that telehealth services be so analogous to in-person care such that the telehealth service is essentially a substitute for a face-to-face encounter. However, these audio-only telephone E/M services are inherently non-face-to-face services, since they are furnished exclusively through remote, audio-only communications. Outside the circumstances of the PHE, the telephone E/M services would not be analogous to in-person care; nor would they be a substitute for a face-to-face encounter. Therefore, we do not believe it will be appropriate for these codes to remain on the Medicare Telehealth Services List after the end of the PHE and the 151-day post-PHE extension period. Accordingly, we did not propose to keep these telephone E/M services on the Medicare Telehealth Services List after that period on a Category 3 basis, because the codes describe services that can only be furnished using audio-only telecommunications technology, and outside of the circumstances of the PHE, they do not describe services that are a substitute for an in-person visit. While we acknowledge that audio-only technology can be used to furnish mental health telehealth services to patients in their homes under certain circumstances after the PHE ends, two-way, audio-video communications technology continues to be the appropriate standard that will apply for Medicare telehealth services after the PHE and the 151-day extension period. As we noted in the CY 2021 PFS final rule (85 FR 84535), we will assign these Telephone E/M visit codes (CPT codes 99441, 99442, and 99443) a ''bundled'' status after the end of the PHE and the 151-day extension period, and we will post the RUC-recommended RVUs for

these codes in accordance with our usual practice.

We received public comments on Telephone E/M Services. The following is a summary of the comments we received and our responses.

Comment: Many commenters urged us to continue to make payment for Telephone E/M visit codes following 151 days after the PHE. Some commenters stated that payment for these services should be made permanent while others request that they be added to the Medicare Telehealth Services List on a Category 3 basis. Commenters stated that experience during the PHE indicated that telehealth can provide a viable alternative to office visits. Commenters stated that, although patient-provider communication using both audio and visual modes is considered optimal for telehealth delivery, many patients are unable to use the video technology required due to lack of broadband or cellular data, technology that does not support video, or difficulty in using video technology. Commenters cited access concerns, particularly for patients who live in rural areas or who lack of broadband access, as well as disparities in access to technology and in digital literacy.

A commenter noted that, in the CY 2023 PFS proposed rule, CMS further stated that telephone E/M services are neither analogous to an in-person E/M visit nor can the telephone E/M substitute for an in-person E/M visit. However, as noted above, in the second IFC, CMS did believe telephone E/Ms were serving as a substitute for in-person E/M visits, and because of that, began to reimburse them the same rate as in-person E/M visits. Commenters noted that this would indicate they are analogous to an in-person service and would fit the criteria to be on the Medicare Telehealth Services List permanently.

Response: We reiterate that we believe these audio-only telephone E/M services are inherently non-face-to-face services, since they are furnished exclusively through remote, audio-only communications. We continue to believe that, outside the circumstances of the PHE, these services will no longer serve as a substitute for in-person care that is ordinarily furnished in a face-to-face encounter. Section 1834(m)(1) of the Act requires that we make payment for telehealth services ''notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary.'' Section 1834(m)(2)(A) of the Act requires that we make payment to a physician or practitioner located at a distant site for a telehealth service at an amount equal to the amount that the physician or practitioner would have been paid if the service had instead been furnished without the use of a telecommunications system. Taken together, we believe that the statute requires that Medicare telehealth services be analogous to in-person care such that the telehealth service is essentially a substitute for a face-to-face encounter. We recognize that we added the telephone E/M services to the Medicare Telehealth Services List on a temporary basis during the PHE to address the associated extraordinary public health and safety, and healthcare access issues. However, outside of the circumstances of the PHE, we continue to believe that our longstanding regulatory interpretation of ''telecommunications system'' generally precludes the use of audio-only technology for purposes of Medicare telehealth services, with the exception under certain circumstances of telehealth services to diagnose, evaluate, or treat a mental health disorder (including treatment of a diagnosed SUD or co-occurring mental health disorder). That rule and the exception are specified in our regulation at § 410.78(a)(3). At the conclusion of the PHE and the 151-day extension period provided by the CAA, 2022, the only Medicare telehealth services that will be permitted to be furnished using audio-only technology will be the mental health telehealth services. When a practitioner furnishes such an E/M service using audio-only technology, they would bill for the same service they would bill if the service had been furnished in person. As such, there is not a need to add the telephone-only E/M codes to the Medicare Telehealth Services List for this purpose.

Comment: A commenter stated that, if CMS removes the telephone E/M CPT codes 99441–99443 from the Medicare Telehealth Services List on the 152nd day after the PHE ends, CMS should then create and establish particular values for a third and higher level of virtual check-in service that would be similar to the telephone E/M services that have been available during the PHE. The commenter is requesting that this third virtual check-in code would crosswalk to CPT code 99443, and should assign RVUs to HCPCS codes G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*), G2252 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion*), and a third potential check-in code with crosswalks to CPT codes 99441–99443, respectively.

Response: We appreciate the comment and may consider potential coding revisions for future rulemaking. However, we believe that, in light of the fact that the virtual check-in codes are intended for practitioners to have a non-face-to-face discussion with a patient to determine the need for care, the necessity for a longer virtual check-in (for example, 21–30 minutes) is not clear. Moreover, if a patient requires evaluation and management (E/M) services that are sufficiently complicated to last longer than the 11–20 minutes considered in HCPCS code G2252, then there are many other E/M visit codes that are already available as Medicare telehealth.

After consideration of public comments, we are finalizing our proposal not to add these CPT codes 99441–99443 to the Medicare Telehealth Services List on a Category 3 basis; rather, we will retain CPT codes 99441–99443 on the Medicare Telehealth Services List through expiration of the 151-day period following the end of the PHE, at which point they will revert to bundled status.

(3) GI Tract Imaging and Continuous Glucose Monitoring

We received requests to add CPT codes describing GI Tract Imaging, CPT code 91110 (*Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report*) and Ambulatory Continuous Glucose Monitoring, CPT code 95251 (*Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report*), to the Medicare Telehealth Services List on a Category 3 basis. We believe these codes may describe services that are inherently non-face-to-face services, (the patient need not be

present in order for the service to be furnished in its entirety), and therefore, they do not describe services that are a substitute for an in-person visit. As stated earlier, we believe that the statute requires that telehealth services be so analogous to in-person care such that the telehealth service is essentially a substitute for a face-to-face encounter. For this and other reasons, we did not propose to add these services to the Medicare Telehealth Services List on a Category 3 basis; we do not believe these CPT codes describe services that are a substitute for an in-person visit, and we believe that services that are not inherently face-to-face services are not services that can be furnished as Medicare telehealth services. Even so, we are interested in information that would help us to understand whether these services would meet the criteria for inclusion on the Medicare Telehealth Services List either for the PHE, as Category 3 services, or permanently on a Category 1 or 2 basis, given our questions as to whether they are inherently non-face-to-face services, and therefore, may not fit within the scope of services that could be furnished as Medicare telehealth services. Therefore, we also solicited comment on whether these services would involve an in-person service when furnished without the use of a telecommunications system.

We received public comments on GI Tract Imaging and Continuous Glucose Monitoring. The following is a summary of the comments we received and our responses.

Comment: A commenter agreed that CPT code 91110 describes a service that is inherently a non-face-to-face service, as the patient is not present in order for the service to be furnished in its entirety. The commenter described the services as involving swallowing a capsule camera that captures images of the gastrointestinal tract, which are recorded on the capsule and subsequently reviewed by the clinician using special computer software. The commenter stated that the ingestion of the capsule is the only component of this service that requires direct observation by a health care provider. The commenter noted that less than 10 percent of the service time/work associated with CPT code 91110 involves any direct interaction with the patient, and the small amount of patient interaction can be done safely and effectively via a telehealth visit with video, per the FDA clearance.

According to one commenter, since the capsule service should only be offered to an established patient, an in-person interaction to administer the capsule is unnecessary and the patient can safely do so in the home setting.

Response: We appreciate this background information from the commenters. Given that this service describes collection, interpretation, and reporting, we believe this code describes services that are not inherently non-face-to-face, and therefore, they do not describe a service that is a substitute for an in-person visit. Additionally, the face-to-face portion of the service would require the patient to be physically present.

Comment: Some commenters agreed with CMS' assessment that Ambulatory Continuous Glucose Monitoring, CPT code 95251, is an inherently non-face-to-face service, and therefore, does not describe a service that is a substitute for an in-person visit. CPT code 95251 does not involve an in-person visit when furnished without the use of a telecommunications system.

One commenter opposed our proposal not to add CPT code 95251 to the Medicare Telehealth Services List on a Category 3 basis, citing the importance of this service in treating gestational diabetes, saying CMS should add CPT code 95251 to the list on a Category 3 basis when it is billed with CPT codes 99213 (*Established patient office or other outpatient visit, 20–29 minutes*) or 99214 (*Established patient office or other outpatient visit, 30–39 minutes*) and the appropriate modifier. Another commenter cited 2020 claims data that shows CPT code 95251 is billed 8.2 percent and 62.6 percent of the time with CPT codes 99213 and 99214, respectively, demonstrating that this service is typically performed face-to-face.

Response: We appreciate the comments. We continue to believe, and commenters have confirmed, that CPT code 95251 is not a substitute for an in-person visit, as this code describes physician analysis, interpretation, and reporting, which does not inherently describe a face-to-face encounter. Accordingly, this code does not describe a service that, when conducted via telehealth, is a substitute for a face-to-face service. As noted in the CY 2018 PFS final rule (82 FR 53011), if a service does not describe a service typically furnished in-person, it would not be considered a telehealth service under the applicable provisions of the statute.

After consideration of public comments, we are finalizing our proposal not to add CPT code 91110 or CPT code 95251 to the Medicare Telehealth Services List on a Category 3 basis.

(4) Neurostimulator Pulse Generator/Transmitter

We received requests to add codes describing the electronic analysis of an implanted neurostimulator pulse generator/transmitter to the Medicare Telehealth Services List. These included a request to add CPT codes 95976 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*) and 95977 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*) permanently on a Category 1 basis, as well as a request to add CPT codes 95970 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming*), 95983 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15*

minutes face-to-face time with physician or other qualified health care professional), and 95984 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)*) to the Medicare Telehealth Services List on a temporary Category 3 basis.

The request to add CPT codes 95976 and 95977, which are codes that describe analysis of cranial nerve neurostimulation, indicated that the ability to fully furnish this service using two-way, audio-video communication technology was forthcoming, but is currently unavailable. Therefore, we did not propose to add CPT codes 95976 and 95977 to the Medicare Telehealth Services List, because the full scope of service elements described by these codes cannot currently be furnished via two-way, audio-video communication technology. However, we will consider additional evidence regarding the ability to furnish these services as telehealth services, such as information indicating that current technology has evolved, as it becomes available for future rulemaking. We also did not propose to add them on a Category 1 basis because they do not describe services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare Telehealth Services List.

With regard to CPT codes 95970, 95983, and 95984, which describe general brain nerve neurostimulation, we have some concerns about whether the full scope of service elements could be furnished via two-way, audio-video communication technology, particularly since it is unclear whether the connection between the implanted device and the analysis/calibration equipment can be done remotely. Additionally, we are concerned about the immediate safety of the patient if the calibration of the neurostimulator were done incorrectly or if some other problem occurred. However, we did include these services on the Medicare Telehealth Services List on a temporary basis during the PHE, and Medicare claims data suggest that these services are being provided via telehealth. Based on this information, we believe there is some possible clinical benefit for these services when furnished via telehealth; however, there is not yet sufficient evidence available to consider the services for permanent addition to the Medicare Telehealth Services List under the Category 1 or Category 2 criteria. With that said, CPT codes 95970, 95983, and 95984 do meet the criteria for temporary inclusion on the Medicare Telehealth Services List on a Category 3 basis. Therefore, we proposed to add CPT codes 95970, 95983, and 95984 to the Medicare Telehealth Services List on a Category 3 basis, while we solicited comment on our concerns regarding patient safety and whether these services are appropriate for inclusion on the Medicare Telehealth Services List outside the circumstances of the PHE.

Comment: Commenters agreed with CMS that the full scope of service elements described by CPT codes 95976 and 95977 cannot currently be furnished via two-way, audio-video communication technology, and they state that the agency should reconsider these services for possible addition to the Medicare Telehealth Services List as evidence develops regarding the ability to furnish these services as telehealth services.

Response: We appreciate commenters' support for this proposal and are finalizing our proposal to not add these services to the Medicare Telehealth Services List.

Comment: Commenters supported our proposal to add CPT codes 95970, 95983, and 95984 to the Medicare Telehealth Services List on a Category 3 basis. Some commenters expressed disappointment that we did not propose to add them to the Medicate Telehealth Services List permanently. In response to our comment solicitation regarding patient safety concerns, a commenter noted that the technology includes safety features, including a prominent network status indicator that appears on both the clinician's programmer, as well as the patient's device, and the ''Protected Recovery Program'' (PRP) feature that ensures the patient is returned to a known state if a remote session is interrupted. According to one commenter, systems have been successfully in use for over a year and a half that allow for a stable, secure 2-way telehealth connection for brain stimulator pulse generator programming. Commenters stated that these systems route through a secure HIPAA-compliant server and allow the managing physician qualified health care professional (QHP) to remotely control all essential functions of the patient device while providing real time audio and video to allow for patient assessment and feedback. The commenter noted that CMS' concerns regarding patient safety if the programming is incorrect or if another problem occurred have been addressed in the development and deployment of existing remote brain neurostimulator programming systems. The commenter stated that these systems ensure that the patient controller has a ''safe'' program (set of stimulation parameters). In the event of an interruption in the remote connection, they noted that the device automatically reverts to this ''safe'' program, so that the patient is not left with a potentially problematic set of programming parameters.

The commenter also noted that all elements can be fully and effectively performed by a remotely located clinician using two-way, audio/video telecommunication technology including direct programming of implantable neurostimulator devices, and these services are critical to the successful therapy regimens and health outcomes of people with Parkinson's disease.

Response: We continue to believe that these services are most appropriately added to the Medicare Telehealth Services on a Category 3 basis. Adding them on a Category 3 basis will allow the continued collection of information through the experiences of clinicians who are furnishing these services via telehealth during the PHE for COVID–19, and help us to determine whether these services may ultimately be eligible for addition to the Medicare Telehealth Services List on a Category 1 or Category 2 basis. We encourage interested parties to use this extended time period to gather data on these services to support their potential addition to the Medicare Telehealth Services List on a Category 1 or Category 2 basis in the future.

After consideration of public comments, we are finalizing our proposals not to add CPT codes 95976 and 95977 to the Medicare Telehealth Services List, and to add CPT codes 95970, 95983, and 95984 to the Medicare Telehealth Services List on a Category 3 basis.

(5) Emotional/Behavior Assessment Services and Psychological or Neuropsychological Testing and Evaluation Services

We received requests to add a number of emotional/behavior assessment services and psychological, or neuropsychological testing and evaluation services, described by CPT codes 97151 (*Behavior identification assessment, administered by a*

physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan), 97152 (*Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes*), 97153 (*Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes*), 97154 (*Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes*), 97155 (*Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes*), 97156 (*Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes*), 97157 (*Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes*), 97158 (*Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes*), 0362T (*Behavior identification supporting assessment, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.*), and 0373T (*Adaptive behavior treatment with protocol modification, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.*) to the Medicare Telehealth Services List permanently on a Category 2 basis. These services are currently on the Medicare Telehealth Services List temporarily for the duration of the PHE. We believe that, for these services, there is likely to be clinical benefit when furnished via telehealth, and therefore, they meet the criteria for temporary inclusion on a Category 3 basis. We did not identify these services during our initial assessment of services that should be temporarily available on the Medicare Telehealth Services List on a Category 3 basis in CY 2021 rulemaking; however, we proposed to include these services on the Medicare Telehealth Services List on a Category 3 basis, in light of information we received from the requestors describing the potential clinical benefit of these services when furnished via telehealth. However, we do have concerns regarding whether, outside the circumstances of the PHE, the full scope of service elements can occur in a manner that does not jeopardize quality of care, whether this patient population could be fully assessed via interactive audio-video technology, and whether these services could be conducted in a way that maintains the safety of the beneficiary. This patient population often includes patients with moderate to severe challenges in oral communication, and they may require close observation of their movements within all of their environmental cues, which include, for instance, smell, sound, and colors around the room. We are concerned that two-way, audio and video communications technology would not fully capture these behavioral nuances. We believe more time may be necessary to develop evidence that could support the decision to add these services to the Medicare Telehealth Services List permanently on a Category 1 or Category 2 basis. We solicited comment on our patient safety concerns.

We received public comments on emotional/behavior assessment and psychological or neuropsychological testing and evaluation services. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the addition of these services on a Category 3 basis. Some commenters suggested that the services should be added permanently, rather than temporarily on a Category 3 basis.

One commenter urged us to permanently add CPT codes 97151, 97152, 97153, 97154, 97155, and 97156, but did not find sufficient evidence supporting safe, effective telehealth delivery of the services represented by codes 97157, 97158, 0362T, or 0373T; however, the commenter supported our proposal to add the latter four codes on a Category 3 basis.

A few commenters responded to our concerns regarding patient safety, quality of care, and whether the full scope of service elements can be met via two-way audio-video communication technology. In response to our questions about regarding whether this patient population can be assessed fully and safely via interactive audio-video technology and our concerns that patients with moderate to severe communication difficulties often require close observation of their responses to cues in their environments (for example, odors, sounds, colors) that could not be accomplished remotely via technology, a commenter acknowledged our concerns, but noted that the services represented by this code set are not specific to any patient population; rather, they noted that they are for any patient for whom they may be medically necessary. The commenter included emerging evidence of the efficacy of telehealth delivery of the services, including research articles relevant to each service. The commenter noted that no reports of significant adverse events or negative side effects were noted in research; however, the commenter indicated that when the assessment or treatment services targeted behaviors in patients with developmental disabilities that carried risk of harm, the supervising behavior analysts (QHPs) had the behavior technicians or caregivers who delivered the services take precautions to protect patients.

A commenter agreed there may be concern that some patients may not be able to be fully assessed via interactive audio-visual technology; however, they stated that the benefits of furnishing these services via telehealth outweigh the concerns. The commenter also noted that the decision as to the appropriateness of care should be determined by the provider, without financial disincentives between in-person and telehealth care. The commenter noted that there are significant benefits to being able to provide these services via telehealth. The commenter stated that patients with dementia or other cognitive or psychological impairments may require the assistance of additional parties

during a visit, and that providing these services remotely can allow for inclusion of other people, including family, significant others, and additional practitioners, who can provide substantial benefits. According to the commenter, this is not always the case for in-person visits, as caregivers and other family members may not be able to take time off from work or travel to the appointments, and virtual visits allow for the practitioner, the patient, and important family members to be in separate locations while still being able to participate in the visit. Additionally, the commenter noted that psychiatric patients often have social anxiety issues, leading to limitations on leaving safe places like their home, facility, or family, and remote visits are important ways to ensure these patients maintain access to care.

A commenter did not support these services remaining on the Medicare Telehealth Services List, stating such additions may pose beneficiary safety and quality-of-care issues. The commenter urged us to exercise extreme caution when adding additional mental-health-related services to the Medicare Telehealth Services List on a temporary basis, considering the unique challenges faced by persons living with mental health conditions, and the multiple, system-wide issues currently complicating the delivery of safe and effective mental health care.

Response: We note that CPT codes 90853 and 96121 are already permanently on the Medicare Telehealth Services List. Regarding CPT codes 96130–96133, 97151–97158, 0362T, and 0373T, we continue to believe our proposal to add these services on a Category 3 basis is appropriate and preferable. Adding these CPT codes to the Medicare Telehealth Services List on a Category 3 basis will allow for the collection and evaluation of data that could potentially support permanent inclusion on the Medicare Telehealth Services List, and we look forward to evaluating such data in the future.

After consideration of public comments, we are finalizing our proposal to retain CPT codes 97151–97158, 0362T, and 0373T on the Medicare Telehealth Services List on a Category 3 basis.

c. Other Services Proposed for Addition to the Medicare Telehealth Services List

As discussed above, there are services that are included on the Medicare Telehealth Services List temporarily during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition to the list under the Category 1 or Category 2 criteria. In addition to the services we proposed for addition to the Medicare Telehealth Services List on a Category 3 basis in response to requests, we also proposed to add a number of services to the Medicare Telehealth Services List on a Category 3 basis that are currently included on the Medicare Telehealth Services List temporarily during the PHE that were not specifically requested for permanent addition. These services would be included on the Medicare Telehealth Services List through 2023 to allow us time to evaluate data that may support their permanent addition to the list on a Category 1 or Category 2 basis.

The services we proposed for addition to the Medicare Telehealth Services List temporarily on a Category 3 basis include CPT codes 90875 (*Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 30 minutes*), 92012 (*Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient*), 92014 (*Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, 1 or more visits*), 92507 (*Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual*), 94005 (*Home ventilator management care plan oversight of a patient (patient not present) in home, domiciliary or rest home (e.g., assisted living) requiring review of status, review of laboratories and other studies and revision of orders and respiratory care plan (as appropriate), within a calendar month, 30 minutes or more*), 96105 (*Assessment of aphasia (includes assessment of expressive and receptive speech and language function, language comprehension, speech production ability, reading, spelling, writing, e.g., by Boston Diagnostic Aphasia Examination*) with interpretation and report, per hour), 96110 (*Developmental screening (e.g., developmental milestone survey, speech and language delay screen), with scoring and documentation, per standardized instrument*), 96112 (*Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour*), 96113 (*Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)*), 96127 (*Brief emotional/behavioral assessment (e.g., depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument), 96170 (Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes*), 96171 (*Health behavior intervention, family (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)*), 97129 (*Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes*), 97130 (*Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; each additional 15 minutes (List separately in addition to code for primary procedure)*), and 99473 (*Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*). Our analyses of these services indicate that there is some evidence of possible clinical benefit associated with these services when furnished via telehealth. We believe these services can safely be furnished via real-time, audio and visual interactive telecommunications under the circumstances of the PHE, but there is not yet sufficient evidence available to consider the services for permanent addition to the Medicare Telehealth Services List under the Category 1 or Category 2 criteria.

Some audiology testing services are currently temporarily included on the Medicare Telehealth Services List for the duration of the PHE. These are CPT codes 92550 (*Tympanometry and reflex threshold measurements*), 92552 (*Pure tone audiometry (threshold); air only), 92553 (Pure tone audiometry (threshold); air and bone*), 92555 (*Speech audiometry threshold;*), 92556 (*Speech audiometry threshold; with speech recognition*), 92557 (*Comprehensive audiometry threshold evaluation and speech recognition (92553 and 92556 combined)*), 92563 (*Tone decay test), 92565 (Stenger test, pure tone*), 92567 (*Tympanometry (impedance testing)*), 92568 (*Acoustic reflex testing, threshold*), 92570 (*Acoustic immittance testing, includes tympanometry (impedance testing), acoustic reflex threshold testing, and acoustic reflex decay testing*), 92587 (*Distortion product evoked otoacoustic emissions; limited evaluation (to confirm the presence or absence of hearing disorder, 3–6 frequencies) or transient evoked otoacoustic emissions, with interpretation and report*), 92588 (*Distortion product evoked otoacoustic emissions; comprehensive diagnostic evaluation (quantitative analysis of outer hair cell function by cochlear mapping, minimum of 12 frequencies), with interpretation and report*), 92601 (*Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming*), 92625 (*Assessment of tinnitus (includes pitch, loudness matching, and masking)*), 92626 (*Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); first hour*), 92627 (*Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); each additional 15 minutes (List separately in addition to code for primary procedure)*). We have received information that, during the PHE, certain practitioners have developed the capacity to perform these services using remote technology including specialized equipment inside an audiometric soundproof booth. We believe that, in circumstances in which such equipment is available at the originating site, these services can be furnished in a way in which all of the elements of the services are met and that there is likely to be a clinical benefit when these services are furnished via telehealth. Therefore, we proposed to add these services to the Medicare Telehealth Services List on a Category 3 basis, which will allow these services to be available via telehealth through the end of CY 2023. We solicited comments regarding how widespread the availability of this remote technology is, and whether interested parties believe these services can be furnished in a way that does not jeopardize patient safety or quality of care when these services are furnished remotely.

Additionally, as discussed in section II.F. of this final rule, we proposed to create HCPCS codes G0316 (listed as GXXX1 in our proposed rule)(*Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99223, 99233, and 99236 for hospital inpatient or observation care evaluation and management services). (Do not report G0316 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 993X0). (Do not report G0316 for any time unit less than 15 minutes)*), G0317 (listed as GXXX2 in our proposed rule) (*Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99306, 99310 for nursing facility evaluation and management services). (Do not report G0317 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 993X0,). (Do not report G0317 for any time unit less than 15 minutes)*), and G0318 (listed as GXXX3 in our proposed rule) (*Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99345, 99350 for home or residence evaluation and management services). (Do not report G0318 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99417). (Do not report G0318 for any time unit less than 15 minutes)*) to describe prolonged services associated with certain types of E/M services. These codes will be replacing existing codes that describe prolonged services, specifically inpatient prolonged services CPT codes 99356 (*Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour (List separately in addition to code for inpatient or observation Evaluation and Management service)*) and 99357 (*Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)*). These services are similar to services currently on the Medicare Telehealth Services List, such as CPT codes 99356 and 99357, which were added to the Medicare Telehealth Services List on a Category 1 basis in the CY 2016 rule (80 FR 71060–71062), as well as O/O prolonged service HCPCS code G2212 (*Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)*), which was added to the Medicare Telehealth Services List on a Category 1 basis in the CY 2021 rule (85 FR 84506). Similarly, we believe that these proposed HCPCS G codes will be sufficiently similar to psychiatric diagnostic procedures or O/O visits currently on the Medicare Telehealth Services List to qualify for inclusion on the list on a Category 1 basis. Therefore, we proposed to add proposed HCPCS codes G0316, G0317, and G0318 to the Medicare Telehealth Services List on a Category 1 basis.

Table 12 lists the services that we are finalizing for addition to the Medicare Telehealth Services List on a Category 3 basis. Table 13 lists the services we are finalizing for permanent addition to the Medicare Telehealth Services List on a Category 1 basis.

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TABLE 12: Services Finalized for Addition to the Medicare Telehealth Services List on a Category 3 Basis Through the End of CY 2023

HCPCS	Short Descriptor
90875	Psychophysiological therapy
90901	Biofeedback train any meth
92012	Eye exam estab pat
92014	Eye exam & tx estab pt 1/>vst
92507	Speech/hearing therapy
92550	Tympanometry & reflex thresh
92552	Pure tone audiometry air
92553	Audiometry air & bone
92555	Speech threshold audiometry
92556	Speech audiometry complete
92557	Comprehensive hearing test
92563	Tone decay hearing test
92565	Stenger test pure tone
92567	Tympanometry
92568	Acoustic refl threshold tst
92570	Acoustic immitance testing
92587	Evoked auditory test limited
92588	Evoked auditory tst complete
92601	Cochlear implt f/up exam <7
92625	Tinnitus assessment
92626	Eval aud funcj 1st hour
92627	Eval aud funcj ea addl 15
94005	Home vent mgmt supervision
95970	Alys npgt w/o prgrmg
95983	Alys brn npgt prgrmg 15 min
95984	Alys brn npgt prgrmg addl 15
96105	Assessment of aphasia
96110	Developmental screen w/score
96112	Devel tst phys/qhp 1st hr
96113	Devel tst phys/qhp ea addl
96127	Brief emotional/behav assmt
96170	Hlth bhv ivntj fam wo pt 1st
96171	Hlth bhv ivntj fam w/o pt ea
97129	Ther ivntj 1st 15 min
97130	Ther ivntj ea addl 15 min
97150	Group therapeutic procedures
97151	Bhv id assmt by phys/qhp
97152	Bhv id suprt assmt by 1 tech
97153	Adaptive behavior tx by tech
97154	Grp adapt bhv tx by tech
97155	Adapt behavior tx phys/qhp
97156	Fam adapt bhv tx gdn phy/qhp
97157	Mult fam adapt bhv tx gdn
97158	Grp adapt bhv tx by phy/qhp
97530	Therapeutic activities
97537	Community/work reintegration
97542	Wheelchair mngment training
97763	Orthc/prostc mgmt sbsq enc
98960	Self-mgmt educ & train 1 pt
98961	Self-mgmt educ/train 2-4 pt
98962	Self-mgmt educ/train 5-8 pt
99473	Self-meas bp pt educaj/train
0362T	Bhv id suprt assmt ea 15 min
0373T	Adapt bhv tx ea 15 min

TABLE 13: Services Finalized for Permanent Addition to the Medicare Telehealth Services List on a Category 1 Basis

HCPCS	Short Descriptor
G0316	Prolonged inpatient or observation services by physician or other QHP
G0317	Prolonged nursing facility services by physician or other QHP
G0318	Prolonged home or residence services by physician or other QHP
G3002	Chronic pain tx monthly b
G3003	Addition 15m pain mang

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We received public comments on these other services that we proposed for addition to the Medicare Telehealth Services List. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the addition of many of these services on a Category 3 basis.

Response: We appreciate the support for our proposals.

Comment: One commenter stated that ophthalmologic services (92002, 92004, 92012 and 92014) are generally covered via telehealth by other insurance plans, including Medicare Advantage plans and the Veterans Health Administration, and should also be available to Medicare beneficiaries. Commenters supported the addition of CPT codes 92012 and 92014 on a Category 3 basis.

Response: We thank commenters for their support of our proposal, and we are finalizing as proposed the addition of CPT codes 92012 and 92014 to the Medicare Telehealth Services List on a Category 3 basis. We did not identify or propose CPT codes 92002 or 92004 as Medicare telehealth in the proposed rule. As such, discussion of these codes is outside the scope of this rule.

Comment: Regarding our comment solicitation related to patient safety for audiology services, a commenter stated that there is now strong evidence confirming that patients who receive therapy services via telehealth have similar, or even better outcomes, compared to patients who received traditional in-person therapy services (including citations of studies). This commenter cited this evidence in urging us to add these services permanently. A commenter stated that the Veteran's Administration has shown, for many years, that audiology services can be safely provided, via telehealth, without sacrificing patient outcomes or quality of care, and that the technology required to perform these procedures via telehealth, in many cases with the assistance of an audiology assistant or technician at a remote location, is readily available. Commenters requested that many audiology services that are not currently available on the Medicare Telehealth Services List be added on a Category 3 basis.

Response: We appreciate the information provided by commenters, and we may consider this information in future rulemaking. Given support of commenters, as well as information provided, we are finalizing the addition of audiology CPT codes 92550, 92552, 92553, 92555, 92556, 92557, 92563, 92565, 92567, 92568, 92570, 92587, 92588, 92601, 92625, 92626, and 92627 to the Medicare Telehealth Services List on a Category 3 basis, as proposed.

Comment: Commenters supported the addition of the proposed prolonged services HCPCS codes G0316–G0318 permanently on a Category 1 basis, stating that doing so is essential to maintaining consistency with the new coding and payment structure for inpatient E/M services.

Response: We appreciate commenters' support for this proposal. We are finalizing the addition of HCPCS codes G0316, G0317, and G0318 to the Medicare Telehealth Services List on a Category 1 basis, as proposed.

Comment: Numerous commenters requested that we add many services that are temporarily available for the PHE to the Medicare Telehealth Services List that are currently on the list on a temporary basis, but that we did not propose to continue on the list to be available as Medicare telehealth services be added on a Category 3 basis

Response: As discussed above, we identified the services we considered appropriate for addition to the Medicare Telehealth Services List on a Category 3 basis by conducting an internal review to assess those services that may, outside of the circumstances of the PHE, be furnished using the full scope of service elements for their respective service/code via two-way, audio-video communication technology, as though the service were provided in-person. The commenters did not present new information indicating that our analysis was incomplete. Furthermore, because we did not propose to add the services requested by these commenters to the Medicare Telehealth Services List on a Category 3 basis, we found these comments to be outside the scope of the proposed rule.

As discussed in section II.E. of this final rule, we proposed to create two HCPCS G-codes to describe monthly Chronic Pain Management and Treatment services: HCPCS code G3002 (*Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and/or maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing e.g. physical therapy and occupational therapy, complementary and integrative approaches, and community-based care, as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using G3002, 30 minutes must be met or exceeded.)*) and HCPCS code G3003 (*Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month (List separately in addition to code for G3002). (When using G3003, 15 minutes must be met or exceeded.)*).

Comment: As discussed in section II.E.4.(33) in the CY 2023 PFS proposed rule, we solicited comment regarding how best the initial visit and subsequent visits should be conducted (for example, in-person, via telehealth, or the use of a telecommunications system, and any implications for additional or different coding). We also considered whether to add the CPM codes to the Medicare

Telehealth Services List. Many commenters asked us to add CPM services to the Medicare Telehealth Services List. One commenter stated that the CPM code(s) would be appropriate to add on a Category 1 basis, since chronic pain limits patient mobility and a ''silver lining'' of the COVID–19 pandemic is that telehealth flexibilities improved access to pain care. This commenter continued that it can be very burdensome for patients, especially those with ''high impact'' chronic pain, to physically get to doctor appointments, undergo the hardship of driving, walking distances, standing in line, and sitting for long periods in waiting rooms, all of which may exacerbate pain that has been ongoing for days to weeks. The commenter emphasized how important access to telehealth is for this particular group of Medicare patients and urged us to add it to the Medicare Telehealth Services List. One commenter stated that telehealth should be an option, because of geographic factors (rural dwellers are underserved) and life circumstances (child care, transportation), which can make repeated in-person appointments inaccessible. This commenter continued that people with chronic pain can experience challenging issues traveling to see a clinician, and often inquire about the availability of receiving integrative care through telehealth. For these reasons, this commenter recommended that we add the CPM services to the Medicare Telehealth Services List. One commenter stated they believed that telehealth increases self-efficacy in people living with pain. As a middle pathway, another commenter requested that we allow providers to use their discretion when determining if telehealth is appropriate for their patient. Another commenter added that telehealth visits should always be with the agreement of the patient as some people are more comfortable with face-to-face interactions. One commenter noted telehealth is appropriate once patients are established on their care plan, while another commenter suggested that at minimum, telehealth be allowed for all follow up visits.

Response: As discussed earlier in this section, we agree with the commenter's suggestion to add CPM services to the Medicare Telehealth Services List on a Category 1 basis. We believe that the interactions between the furnishing practitioner and the beneficiary described by the required face-to-face visit component of the CPM services are sufficiently similar to professional consultations, office visits, and office psychiatry services currently on the Medicare Telehealth Services List for these services to be added on a Category 1 basis. By its nature, and because of the many treatment challenges described by these and other commenters in section II.E.4.(33), pain care is ideally suited to telehealth, and we believe appropriate to be furnished through interactive, real-time telecommunications technology. Like certain other non-face-to face PFS services, there are also components of HCPCS codes G3002 and G3003 describing care planning or care coordination with other health care professionals that are commonly furnished remotely using telecommunications technology, and do not require the patient to be present/in-person with the practitioner when they are furnished. As such, these components of HCPCS codes G3002 and G3003 are not considered telehealth services for purposes of Medicare, and we do not need to consider whether the non-face-to-face aspects of HCPCS codes G3002 and G3003 are similar to other telehealth services. We are finalizing in this rule that any of the CPM in-person components included in HCPCS codes G3002 and G3003 may be furnished via telehealth, as clinically appropriate, in order to increase access to care for beneficiaries. However, we reiterate as provided in the code descriptor that the initial CPM services visit billed under HCPCS code G3002 must be furnished in-person without the use of telecommunications technology. (For further clarification about the initial in person visit requirements, please see section II.E.4.(33).)

Comment: One commenter asked that we enable the CPM codes, in addition to being rendered through telehealth, to be furnished through audio-only technology.

Response: We appreciate the comment. In the CY 2022 PFS final rule, we finalized a policy to revise the definition of ''telecommunications system'' at § 410.78(a)(3) to allow the use of audio-only technology for the diagnosis, evaluation, or treatment of mental health conditions under certain circumstances (described in detail at 86 FR 64996, 65056 through 65060) that allow visits and other services furnished via audio-only technology to be reported as Medicare telehealth services, with the appropriate modifier. We acknowledge that certain scope of service aspects of CPM may pertain to the diagnosis, evaluation, or treatment of mental health conditions. We expect clinicians will bill for the HCPCS code that most accurately describes the services furnished, including in instances where the service being furnished might determine the technological modality used to deliver the service.

After consideration of public comments, we are finalizing our proposal to add CPT codes 90875, 92012, 92014, 92507, 94005, 96105, 96110, 96112, 96113, 96127, 96170, 96171, 97129, 97130, and 99473 to the Medicare Telehealth Services List on a Category 3 basis, and finalizing our proposal to add HCPCS codes G0316, G0317, and G0318, G3002, and G3003 to the Medicare Telehealth Services List on a Category 1 basis.

d. Services Proposed for Removal From the Medicare Telehealth Services List After 151 Days Following the End of the PHE

As we noted in the CY 2022 PFS final rule (86 FR 65054), at the conclusion of the PHE for COVID–19, the associated waivers and interim policies will expire, payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Act, and we will return to the policies established through our regular notice-and-comment rulemaking process, through which we established and maintain the Medicare Telehealth Services List. Services that have been added to the Medicare Telehealth Services List on a Category 3 basis will remain on the list through the end of CY 2023. We have explained that under our current policy, all other services that were temporarily added to the Medicare Telehealth Services List on an interim basis during the PHE and have not been added to the Medicare Telehealth Services List on a Category 1, 2, or 3 basis will not remain on the list after the end of the PHE (85 FR 84506–84509). As explained in section II.D.1.e. of this final rule, Division P, Title III, Subsection A of the Consolidated Appropriations Act, 2022 (CAA, 2022), extends some of the flexibilities implemented during the PHE for COVID–19 for an additional 151 days after the end of the PHE, including section 301(a) of Division P, Title III, Subtitle A of the CAA, 2022, which specifies that, for services on the Medicare Telehealth Services List as of the date of enactment (March 15, 2022) furnished during 151 days after the end of the PHE, the originating site for the telehealth service can be any site in the United States at which the beneficiary is located when the service is furnished, including the beneficiary's home. To give full effect to this provision, we believe it is necessary to continue to include the services on the Medicare Telehealth Services List through the 151-day period after the end of the PHE that were temporarily added to the list

during the PHE but have not since been added on a Category 3 or other basis, and which are currently set to be removed from the list at the end of the PHE. As such, we proposed to continue to include on the Medicare Telehealth Services List the services that are currently set to be removed from the list when the PHE ends (that is, those not currently added to the list on a Category 1, 2, or 3 basis) for an additional 151 days after the PHE ends. Table 14 lists those services that are temporarily included on the list available for the PHE, which we proposed to retain on the Medicare Telehealth Services List for an additional 151 days following the end of the PHE. The services listed in Table 14 will no longer be available on the Medicare Telehealth Services List on the 152nd day after the end of the PHE. As previously explained, on the 152nd day after the end of the PHE, payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Act, as aforementioned, and telehealth claims for these services furnished on or after the codes are removed from the list will be denied. We proposed to align the temporary availability of services available as Medicare telehealth services until the end of the PHE with the 151-day extensions of flexibilities enacted in the CAA, 2022 in order to simplify the process of ending the PHE-related flexibilities and to minimize possible errors.

Comment: A commenter noted that CPT code 94664 did not appear in Table 10 of the proposed rule despite being a code that was temporarily added for the PHE.

Response: We agree that CPT code 94664 was inadvertently omitted from Table 10 of the proposed rule. As a code that was temporarily added to the Medicare Telehealth Services List for the duration of the PHE, it should have been included among codes that we proposed will remain on the Medicare Telehealth Services List for an additional 151 days following the end of the PHE. We have corrected this error in Table 14, and we are finalizing that CPT code 94664 will remain on the Medicare Telehealth Services List for an additional 151 days following the end of the PHE.

Comment: Many commenters supported our proposal to align the period of availability for services that are temporarily available for the duration of the PHE with the 151-day extension of certain telehealth flexibilities associated with the CAA, 2022. Some commenters stated that we should eliminate the temporary designation for all services on the Medicare Telehealth Services List, making permanent all services currently available.

Response: We thank commenters for their support of our proposal to allow services that would be available for the duration of the PHE to remain on the Medicare Telehealth Services List through the 151-day period following the end of the PHE. We continue to believe that services, including those that we added on a temporary interim basis for the PHE for COVID–19, should be considered for permanent addition to the Medicare Telehealth Services List through the regular annual process we established as required by section 1834(m)(4)(F)(ii) of the Act. While we have included some services on the Medicare Telehealth Services List on a temporary Category 3 basis through the end of CY 2023, this was to allow for the continued development of data to support their potential future consideration for permanent addition to the list on a Category 1 or Category 2 basis; we review all items on the Medicare Telehealth Services List each year as per our established process. Interested parties may continue to use the annual submission process to request the addition of any services to or deletion of services from the Medicare Telehealth Services List, regardless of whether the service was added on a temporary Category 3 basis. We note that the services that are included on the Medicare Telehealth Services list on a Category 3 basis will remain on the list for an additional period beyond 151 days after the end of the PHE, which is currently through the end of 2023. We understand that, if the PHE is in effect for most of the year next year, the 151-day period after the PHE may end on a date that is beyond December 31, 2023. We clarify that in this instance, the Category 3 services would remain on the Medicare Telehealth Services List through December 31, 2023 or 151 days after the PHE, if later. We will consider whether any additional extensions are needed in the future.

TABLE 14: Services to be Removed from the Medicare Telehealth Services List After 151 Days Following End of the PHE

HCPCS	Short Descriptor
77427	Radiation tx management x5
92002	Eye exam new patient
92004	Eye exam new patient
93750	Interrogation vad in person
94002	Vent mgmt inpat init day
94003	Vent mgmt inpat subq day
94004	Vent mgmt nf per day
94664	Evaluate pt use of inhaler
96125	Cognitive test by hc pro
99218	Initial observation care
99219	Initial observation care
99220	Initial observation care
99221	Initial hospital care
99222	Initial hospital care
99223	Initial hospital care
99234	Observ/hosp same date
99235	Observ/hosp same date
99236	Observ/hosp same date
99304	Nursing facility care init
99305	Nursing facility care init
99306	Nursing facility care init
99324	Domicil/r-home visit new pat (deleted from the PFS for CY 2023)
99325	Domicil/r-home visit new pat (deleted from the PFS for CY 2023)
99326	Domicil/r-home visit new pat (deleted from the PFS for CY 2023)
99327	Domicil/r-home visit new pat (deleted from the PFS for CY 2023)
99328	Domicil/r-home visit new pat (deleted from the PFS for CY 2023)
99341	Home visit new patient
99342	Home visit new patient
99343	Home visit new patient (deleted from the PFS for CY 2023)
99344	Home visit new patient
99345	Home visit new patient
99441	Phone e/m phys/qhp 5-10 min
99442	Phone e/m phys/qhp 11-20 min
99443	Phone e/m phys/qhp 21-30 min
99468	Neonate crit care initial
99471	Ped critical care initial
99475	Ped crit care age 2-5 init
99477	Init day hosp neonate care

e. Implementation of Telehealth Provisions of the Consolidation Appropriations Acts, 2021 and 2022

As discussed in the CY 2021 PFS final rule (85 FR 84506), legislation enacted to address the PHE for COVID–19 provided the Secretary with new authorities under section 1135(b)(8) of the Act, as added by section 102 of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 116–123, March 6, 2020) and subsequently amended by section 6010 of the Families First Coronavirus Response Act (Pub. L. 116–127, March 18, 2020) and section 3703 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020), to waive or modify Medicare telehealth payment requirements during the PHE for COVID–19. We used these authorities to establish several flexibilities to accommodate changes in the delivery of care during the PHE. Through waiver authority under section 1135(b)(8) of the Act, in response to the PHE for COVID–19, we removed the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act, as well as restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services, for the duration of the PHE for COVID–19. We also used waiver authority to allow certain telehealth services to be furnished via audio-only communication technology. At the end of the PHE for COVID–19, these waivers and interim policies will expire, and payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Act.

Section 1834(m)(7) of the Act (as added by section 2001(a) of the SUPPORT for Patients and Communities Act (Pub. L. 115–271, October 24, 2018)), removes the geographic restrictions under section 1834(m)(4)(C)(i) of the Act and authorizes the patient's home as a permissible originating site, for telehealth services furnished for purposes of treatment of a substance use disorder (SUD) or a co-occurring mental health disorder, furnished on or after July 1, 2019, to an individual with a SUD diagnosis. Section 123(a) of Division CC of the Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020) amended section 1834(m)(7)(A) of the

Act to broaden the scope of services for which the geographic restrictions under section 1834(m)(4)(C)(i) of the Act do not apply and for which the patient's home is a permissible originating site to include telehealth services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the end of the PHE for COVID–19. Section 123(a) of the CAA, 2021 also added subparagraph (B) to section 1834(m)(7) of the Act to prohibit payment for a telehealth service furnished in the patient's home under paragraph (7), unless the physician or practitioner furnishes an item or service in-person, without the use of telehealth, within 6 months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary, and thereafter, at such times as the Secretary determines appropriate. For a full discussion of our implementation of section 123(a) of the CAA, 2021, refer to our CY 2022 PFS final rule (86 FR 64996).

In the proposed rule, we proposed to implement provisions of section 1834(m) of the Act (including the amendments made by the CAA, 2021) and provisions of the CAA, 2022 that extend certain Medicare telehealth flexibilities adopted during the PHE for 151 days after the end of the PHE.

Sections 301, 302, 303, 304, and 305 of Division P, Title III, Subtitle A of the CAA, 2022 amended section 1834(m) of the Act to generally extend certain PHE-related telehealth policies for services that are on the Medicare Telehealth Services List as of the date of enactment (March 15, 2021). Specifically, section 301(a) of the CAA, 2022 amended section 1834(m)(4)(C) of the Act to add a new clause (iii), which temporarily expands the scope of telehealth originating sites for those services to include any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home, for a 151-day period beginning on the first day after the end of the PHE for COVID–19. Section 301(a) also amended section 1834(m)(7)(A) of the Act to apply the expanded scope of telehealth originating site policy to include any location in the United States in new clause (iii) of section 1834(m)(4)(C) of the Act during the 151-day period for telehealth services furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and to individuals with a SUD diagnosis for purposes of treatment of the SUD or a co-occurring mental health disorder for this 151-day post-PHE extension period. In addition to this provision, section 301(b) of the CAA, 2022 amended section 1834(m)(2)(B) of the Act to add a new clause (iii) that allows payment of an originating site facility fee to an originating site with respect to those telehealth services furnished during the 151-day period only if the originating site is one that meets the geographic requirements in section 1834(m)(4)(C)(i) of the Act, and is a setting included on the enumerated list of originating sites under section 1834(m)(4)(C)(ii) of the Act (other than the patient's home).

Section 302 of the CAA, 2022 amended section 1834(m)(4)(E) of the Act to temporarily expand the definition of eligible telehealth practitioners for the 151-day period beginning on the first day after the end of the PHE for COVID–19 to include qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists.

Section 303 of the CAA, 2022 amended section 1834(m)(8) of the Act to temporarily continue payment for telehealth services furnished by FQHCs and RHCs for the 151-day period beginning on the first day after the end of the COVID–19 PHE using the methodology established for telehealth services furnished by FQHCs and RHCs during the PHE, which, in accordance with section 1834(m)(8)(B) of the Act, is based on payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS.

Section 304(a) of the CAA, 2022 amended section 1834(m)(7)(B)(i) of the Act to delay the requirement for an in-person visit with the physician or practitioner within 6 months prior to the initial mental health telehealth service, and again at subsequent intervals as the Secretary determines appropriate. In light of this amendment, the in-person requirements for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder will again be effective on the 152nd day after the PHE ends. In addition, section 304(b) and (c) of the CAA, 2022 modified sections 1834(y) and 1834(o)(4) of the Act, respectively, to similarly delay in-person visit requirements for mental health visits furnished by Rural Health Clinics and Federally Qualified Health Centers via telecommunications technology. Therefore, we proposed to revise the regulatory text at § 410.78(b)(3)(xiv) to recognize the delay of the in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare until the 152nd day after the PHE for COVID–19, to conform with the statute. See section II.B.3. of this final rule for our proposal to implement similar changes for RHC and FQHC mental health visits.

Finally, section 305 of the CAA, 2022 added a new paragraph (9) to section 1834(m) of the Act to require the Secretary to continue to provide for coverage and payment of telehealth services included on the Medicare Telehealth Services List as of the March 15, 2022, date of enactment that are furnished via an audio-only telecommunications system during the 151-day period beginning on the first day after the end of the PHE for COVID–19. The new paragraph applies only to telehealth services specified on the Medicare Telehealth Services List under section 1834(m)(4)(F)(i) of the Act that are designated to as eligible to be furnished via audio-only technology as of the date of enactment of the CAA, 2022 (that is, March 15, 2022). These are the services for which CMS waived the requirements of section 1834(m)(1) of the Act and the first sentence of § 410.78(a)(3) for use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology, during the PHE. Under this waiver, CMS permitted the audio-only telephone E/M services and certain behavioral health counseling and educational services to be furnished via audio-only equipment during the PHE for COVID–19. We proposed to continue to make payment for services included on the Medicare Telehealth Services List as of March 15, 2022 that are furnished via an audio-only telecommunications system for the 151-day period beginning on the first day after the end of the PHE. We read section 305 of the CAA, 2022 to require that we continue to make payment for services furnished via audio-only telecommunications systems (each described by a HCPCS code, including their successor codes) for the 151-day period after the end of the PHE. These services include certain behavioral health, counseling, and educational services. (*https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf*, n.d.). A list of the services that involve audio-only interaction but are included on the Medicare Telehealth Services List for the duration of the PHE is available at the CMS website, *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes*.

Section 309 of Division P, Title III, Subtitle A of the CAA, 2022 authorizes the Secretary to implement the amendments described above made by

sections 301 through 305 through program instruction or otherwise. Given that the end date of the PHE is not yet known and could occur before the rulemaking process for the CY 2023 PFS is complete, and that the changes made by these provisions are very specific and concise, we announced in the CY 2023 PFS proposed rule that we intended to issue program instructions or other subregulatory guidance to effectuate the changes described above, other than the proposed revisions to § 410.78. We intend to issue these instructions in the near future. We believe this approach will serve to ensure a smooth transition after the end of the PHE for COVID–19.

We received public comments on our proposals to implement section 304(a) of the CAA, 2022, which amended section 1834(m)(7)(B)(i) of the Act, regarding the requirement that an in-person visit with the physician or practitioner must occur within 6 months prior to the initial mental health telehealth service. The following is a summary of the comments we received and our responses.

In-Person Requirements

Comment: Many commenters expressed general support for our proposals to implement and effectuate changes via program instructions, and subregulatory guidance, based on the fact that the last day of the PHE remains uncertain, but varied in their level of concern about whether the post-PHE transition period, of 151 days, would allow enough flexibility. Commenters expressed concerns that a sudden shift in the in-person visit requirements, beginning 152 days after the end of the PHE, could create beneficiary access issues, additional strain on the existing health care workforce shortage, and significant confusion among clinical and administrative staff about how to align resources and inform beneficiaries. Some commenters noted that the public will receive only 60 days' notice before the last day of the PHE, which they believe would not allow adequate time to coordinate in-person care across many different settings of care and varied individual beneficiary needs. A few commenters suggested that CMS should take the narrowest interpretation of the intent of Congress for in-person visit requirements prior to the initial mental health telehealth service, on the basis that the Secretary has the authority to specify the requirements associated with the required interval for similar follow-up in-person visit requirements. Other commenters expressed confusion about how individual physicians or practitioners would ensure appropriate record keeping and overall compliance plans would be updated to provide a means of verifying that any individual service met the in-person visit requirements. Some commenters whose focus is on enabling and supporting telehealth care through various health IT solutions requested that CMS provide more specifics on timing and possible ways to standardize the means by which individual physicians or practitioners document compliance with in-person requirements.

We also received comments that outlined concerns or possible risks to patient safety when patients with certain mental health conditions were treated remotely. These commenters provided examples of high-risk circumstances, such as possible risks associated with treating complex, or atypical patients, via telehealth. Commenters discussed that care of certain patients, who may have a severe or rare diagnosis, may also be under a course of treatment, where that plan of care includes a medication regimen that requires close monitoring. Alternatively, one commenter mentioned that certain beneficiaries with significant complex needs may demonstrate possible outcomes that may be superior when delivered via telehealth versus in-person. We also received a broad range of comments suggesting varied ways that CMS could implement the in-person visit requirements for mental health telehealth services.

Response: We appreciate these commenters' feedback. We did not propose to modify our established policies to implement these in-person visit requirements (except as it pertains to the 151-day extension for the 6-month requirement for an in-person visit for mental health treatment). We recognize that the CAA, 2022 delays implementation of the in-person visit requirements for mental health telehealth services for a period of 151 days after the final day of the PHE. As explained above and in the proposed rule, we are implementing section 304(a) of the CAA, 2022. and further emphasize that the availability of furnishing these services via telehealth does not preclude practitioners from seeing patients in-person, when indicated. We will continue to gather information on these mental health telehealth services as they are utilized, and we will take this information into consideration in the future for possible rulemaking.

Comment: Several commenters suggested that no in-person requirement should be enforced at all.

Response: We appreciate commenters' feedback. The statute does require an in-person, non-telehealth visit within 6 months prior to the first mental health services furnished via Medicare telehealth. However, we clarify that we do not believe this requirement applies to beneficiaries who began receiving mental health telehealth services in their homes during the PHE. In other words, if a beneficiary began receiving mental health telehealth services during the PHE or during the 151-day period after the end of the PHE, then they would not be required to have an in-person visit within 6 months; rather, they will be considered established and will instead be required to have at least one in-person visit every 12 months (so long as any such subsequent telehealth service is furnished by the same individual physician or practitioner (or a practitioner of the same sub-specialty in the same practice) to the same beneficiary). This means that these services would be subject to the requirement that an in-person visit is furnished within 12 months of each mental health telehealth service for those services that are subject to in-person visit requirements (unless an exception is documented by their treating practitioner). For discussion of additional requirements for these services, please see the discussion in the CY 2022 PFS final rule.

f. Use of Modifiers for Medicare Telehealth Services Following the End of the PHE for COVID–19

Prior to CY 2017, Medicare telehealth services furnished via interactive audio and video telecommunications systems were reported using the GT modifier. In the CY 2017 PFS Final Rule, CMS finalized creation of a new Place of Service (POS) code for Medicare telehealth, POS ''02'' (81 FR 80199–80201). When a physician or practitioner submits a claim for their services, including claims for telehealth services, they include a place of service (POS) code that is used to determine whether a service is paid using the facility or non-facility rate. Under the PFS, there are two payment rates for many physicians' services: the facility rate and the non-facility (or office) rate. The PFS non-facility rate is the single amount paid to a physician or other practitioner for services furnished in their office. The PFS facility rate is the amount generally paid to a professional when a service is furnished in a setting of care, like a hospital, where Medicare is making a separate payment to a facility entity in addition to the payment to the billing physician or practitioner. This separate payment, often referred to as a ''facility fee,'' reflects the facility's costs associated with the service (clinical staff, supplies,

and equipment) and is paid in addition to what is paid to the professional under the PFS. POS ''02'' indicates that the service was furnished via telehealth, and under the pre-PHE process, was then paid at the facility payment rate.

As discussed in the March 31, 2020 IFC, (refer to 85 FR 19230), we stated that, as physician practices suddenly transitioned a potentially significant portion of their services from in-person to telehealth visits in the context of the PHE for the COVID–19 pandemic, the relative resource costs of furnishing these services via telehealth may not significantly differ from the resource costs involved when these services are furnished in-person. Therefore, we instructed physicians and practitioners who bill for Medicare telehealth services to report the POS code that would have been reported had the service been furnished in-person. This will allow our systems to make appropriate payment for services furnished via Medicare telehealth, which, if not for the PHE for the COVID–19 pandemic, would have been furnished in-person, at the same rate they would have been paid if the services were furnished in-person. In order to effectuate this change, we finalized on an interim basis (85 FR 19233) the use of the CPT telehealth modifier, modifier ''95'', for the duration of the PHE for COVID–19, which should be applied to claim lines that describe services furnished via telehealth and that the practitioner should report the POS code where the service would have occurred had it not been furnished via telehealth.

We further noted that we are maintaining the facility payment rate for services billed using the general telehealth POS code ''02'', should practitioners choose to maintain their current billing practices for Medicare telehealth during the PHE for the COVID–19 pandemic.

We proposed that Medicare telehealth services furnished on or before the 151st day after the end of the PHE, in alignment with the extensions of telehealth-related flexibilities in the CAA, 2022, will continue to be processed for payment as Medicare telehealth claims when accompanied with the modifier ''95.'' We further proposed that physicians and practitioners can continue to report the place of service code that would have been reported had the service been furnished in-person during the 151-day period after the end of the PHE, as finalized on an interim basis in the March 31 IFC (85 FR 19233). We proposed that Medicare telehealth services performed with dates of service occurring on or after the 152nd day after the end of the PHE will revert to pre-PHE rules and will no longer require modifier ''95'' to be appended to the claim, but the appropriate place of service (POS) indicator will need to be included on the claim to be processed for payment as Medicare telehealth claims in order to properly identify the place where the service was furnished. We further proposed that, for Medicare telehealth services furnished on or after the 152nd day after the end of the PHE, the POS indicators for Medicare telehealth will be:

- POS ''02''—is redefined as Telehealth Provided Other than in Patient's Home (*Descriptor: The location where health services and health related services are provided or received, through telecommunication technology. Patient is not located in their home when receiving health services or health related services through telecommunication technology.*); and
- POS ''10''—Telehealth Provided in Patient's Home (*Descriptor: The location where health services and health related services are provided or received through telecommunication technology. Patient is located in their home (which is a location other than a hospital or other facility where the patient receives care in a private residence) when receiving health services or health related services through telecommunication technology.*).

We remind readers that we defined ''home'' in our CY 2022 PFS final rule (86 FR 65059) to include, as: ''both in general and for this purpose, a beneficiary's home can include temporary lodging, such as hotels and homeless shelters. We also clarified that for circumstances where the patient, for privacy or other personal reasons, chooses to travel a short distance from the exact home location during a telehealth service, the service is still considered to be furnished 'in the home of an individual' for purposes of section 1834(m)(4)(C)(ii)(X) of the Act.''

In our proposed rule, we discussed that, once the flexibilities for the geographic restrictions and the site of service waivers for Medicare telehealth services expire (on the 152nd day after the end of the PHE, per the CAA, 2022), POS ''02'' would once again be required for all Medicare telehealth claims (with the exception of certain Medicare telehealth for mental health services). In the proposed rule, we noted that the exceptions include claims for Medicare telehealth mental health telehealth services, clinical assessments for patients with ESRD that are receiving home dialysis, and Medicare telehealth treatment of an SUD or mental health services that are co-occurring mental health disorder with substance use treatment that are furnished to with the patient in their home (that is, the originating site is in a private residence and not a hospital or other facility setting), in which case POS ''10'' could be used by the billing practitioner. In our proposed rule, we further discussed that, on or after the 152nd day after the PHE has expired, payment for Medicare telehealth services using either of the Medicare telehealth POS codes would be made at the PFS facility payment rate, in accordance with established PFS policy outside the circumstances of the PHE. We proposed to align payment for those telehealth services described as taking place in the beneficiary's home, using POS ''10'' for Medicare telehealth, and those services not provided in a patient's home, using POS ''02'' for Medicare telehealth, to be made at the same facility payment amount. We believe that the facility payment amount best reflects the practice expenses, both direct and indirect, involved in furnishing services via telehealth (please see section II.B. of this final rule for further discussion regarding practice expense).

We further proposed that, beginning January 1, 2023, a physician or other qualified health care practitioner billing for telehealth services furnished using audio-only communications technology shall append CPT modifier ''93'' (*Synchronous Telemedicine Service Rendered Via Telephone or Other Real-Time Interactive Audio-Only Telecommunications System: Synchronous telemedicine service is defined as a real-time interaction between a physician or other qualified health care professional and a patient who is located away at a distant site from the physician or other qualified health care professional. The totality of the communication of information exchanged between the physician or other qualified health care professional and the patient during the course of the synchronous telemedicine service must be of an amount and nature that is sufficient to meet the key components and/or requirements of the same service when rendered via a face-to-face interaction*) to Medicare telehealth claims (for those services for which the use of audio-only technology is permitted under § 410.78(a)(3)), to identify them as having been furnished using audio-only technology. We noted that we have also instructed all relevant providers, including RHCs, FQHCs, and OTPs to append Medicare modifier ''FQ'' (*Medicare telehealth service was furnished using audio-only*

communication technology) for allowable audio-only services furnished in those settings; however, consistent with our proposal for audio-only services furnished under the PFS, we also proposed to require all relevant providers, including RHCs, FQHCs, and OTPs to use modifier ''93'' when billing for eligible mental health services furnished via audio-only telecommunications technology. We believe that using modifier ''93'', which is a CPT modifier, will simplify billing, as this modifier is used by payers outside of Medicare. Currently, these modifiers can only be applied to Medicare telehealth mental health services and those telehealth services for the treatment of a SUD or a co-occurring mental health disorder when the originating site is the beneficiary's home.

Supervising practitioners continue to be required to append the ''FR'' modifier on any applicable telehealth claim when they provide direct supervision for a service using virtual presence through real-time, audio and video telecommunications technology.

Comment: Some commenters expressed concern regarding our proposed approach to the use of modifiers for billing of Medicare telehealth services. One commenter noted that we had inadvertently overlooked the fact that after the transition period, facility-based providers would not be able to bill using the POS code fields, as the CMS–1450 (UB–04) institutional claim form does not permit use of POS code fields. The commenter noted that this may have been an oversight.

Response: We thank commenters for offering feedback on technical issues associated with our proposed policies for use of modifiers that allow claims processing and billing for professional services under Part B, which includes Medicare telehealth services. We reiterate that 151 days after the end of the PHE, Medicare telehealth services will once again be subject to the statutory requirements in section 1834(m) of the Act. As such, only physicians and the practitioners specified in section 1834(m)(4)(E) of the Act will be able to serve as distant site practitioners to furnish and bill for Medicare telehealth services, and those services would be billed on the professional, not the institutional, claim form. Thus, beginning on the 152nd day after the PHE ends, only certain types of practitioners will be permitted to furnish and bill for Medicare telehealth services, and none of those practitioners would be ''facility-based providers.''

Comment: Many commenters requested that we continue to allow for services that would have been furnished in a non-facility setting outside of the circumstances of the PHE to be billed at the non-facility rate for telehealth services following the end of the PHE. Commenters stated that they were concerned that reverting to the facility rate for telehealth services will lead practitioners to offer telehealth less frequently and inhibit access. According to these commenters, many patients in rural and underserved areas are now able to access mental health services, often for the first time. Many commenters emphasized their concerns that mental health services would be particularly impacted, as there is already high demand for these services and relatively low numbers of available practitioners.

One commenter requested that we maintain payment at the non-facility-based rate for telehealth services furnished in office settings through the end of 2023, stating that changing payment to the facility rate would result in a nearly 30 percent cut for some services, which they believed will harm access to telehealth services.

Some commenters, including MedPAC, expressed concern that payment at the facility rate will create the unintended effects of shifting beneficiaries toward both higher intensity and volume of virtual care modalities that would be inappropriate for beneficiaries. In MedPAC's comment, they offered their March 2022 MedPAC Report to Congress (*https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_v2_SEC.pdf*), which noted that Medicare spending can be sensitive to shifts in the site of care, and that the negative impact of the pandemic on E/M services may have been more significant in 2020 were it not for Medicare telehealth.

Some commenters, including MedPAC, provided examples and explanations that raised questions about uncertainty of clinical benefit and possible overpayment for Medicare telehealth and offered evidence that many patients who used telehealth during the PHE would prefer in-person visits, once it is safe to do so.

Response: We acknowledge the commenters' concerns. We note that there are many nuances to this issue, and we seek to minimize confusion and practitioner burden during the period immediately following the PHE. We are concerned about issues raised by commenters related to payment stability in the post-PHE period, as care delivery will potentially be transitioning between virtual, hybrid, and in-person models. As such, we are finalizing that we will continue to allow for payment be made for Medicare telehealth services at the place of service for telehealth services that ordinarily would have been paid under the PFS, if the services were furnished in-person, through the latter of the end of the of CY 2023 or the end of the calendar year in which the PHE ends. For those services furnished in a facility as an originating site, POS 02 may be used, and the corresponding facility fee can be billed, per pre-PHE policy, beginning the 152nd day after the end of the PHE.

Comment: Some commenters expressed concern that our proposals to transition to the use of new modifiers would create confusion and administrative burden, without sufficient time to allow for the sufficient training education of clinical and administrative staff to implement new billing practices. Others supported immediate implementation.

Response: We appreciate commenters' feedback. We believe that the use of these modifiers following the end of the PHE, when implemented, will enable practitioners to better report (and allow CMS to better understand) how they practice and when certain services are furnished via telehealth. We do not agree that these modifiers/codes would cause confusion; rather, they will provide clarity. Moreover, education regarding these modifiers/codes will be made available, as necessary.

After consideration of public comments, we are finalizing our proposals, with some modifications regarding the use of telehealth modifiers/codes and the payment rates. Practitioners will continue to bill with modifier 95 along with the POS code corresponding to where the service would have been furnished in-person through the later of the end of the year in which the PHE ends or CY 2023. As stated earlier, for those services furnished in a facility as an originating site, POS 02 may be used, and the corresponding facility fee can be billed, per pre-PHE policy, beginning the 152nd day after the end of the PHE.

Additionally, effective on and after January 1, 2023, CPT modifier ''93'' can be appended to claim lines, as appropriate, for services furnished using audio-only communications technology in accordance with our regulation at § 410.78(a)(3). All providers, including RHCs, FQHCs, and OTPs must append Medicare modifier ''FQ'' (*Medicare telehealth service was furnished using audio-only communication technology*) for allowable audio-only services furnished in those settings. However,

consistent with our proposal for audio-only services furnished under the PFS, we are also finalizing to require all providers including RHCs, FQHCs, and OTPs to use modifier ''93'' when billing for eligible mental health services furnished via audio-only telecommunications technology. Providers have the option to use the ''FQ'' or the 93'' modifiers or both where appropriate and true, since they are identical in meaning.

Supervising practitioners continue to be required to append the ''FR'' modifier on any applicable telehealth claim when they provide direct supervision for a service using virtual presence through real-time, audio and video telecommunications technology.

In response to the issues raised by commenters related to payment stability in the post-PHE period, we are reiterating that we are finalizing that, for Medicare telehealth services, we will continue to maintain payment at the POS had the service been furnished in-person, and this will allow payments to continue to be made at the non-facility-based rate for Medicare telehealth services through the latter of the end of CY 2023 or the end of the calendar year in which the PHE ends.

2. Other Non-Face-to-Face Services Involving Communications Technology Under the PFS

a. Expiration of PHE Flexibilities for Direct Supervision Requirements

Under Medicare Part B, certain types of services, including diagnostic tests, services incident to physicians' or practitioners' professional services, and other services, are required to be furnished under specific minimum levels of supervision by a physician or practitioner.

For professional services furnished incident to the services of the billing physician or practitioner (see § 410.26) and many diagnostic tests (see § 410.32), direct supervision is required. Additionally, for pulmonary rehabilitation services (see § 410.47) and for cardiac rehabilitation and intensive cardiac rehabilitation services (see § 410.49), direct supervision of a physician is required (see also § 410.27(a)(1)(iv)(D) for hospital outpatient services).Outside the circumstances of the PHE, direct supervision requires the immediate availability of the supervising physician or other practitioner, but the professional need not be present in the same room during the service. We have established this ''immediate availability'' requirement to mean in-person, physical, not virtual, availability (please see the April 6, 2020 IFC (85 FR 19245) and the CY 2022 PFS final rule (86 FR 65062)).

Through the March 31, 2020 COVID–19 IFC, we changed the definition of ''direct supervision'' during the PHE for COVID–19 (85 FR 19245 through 19246) as it pertains to supervision of diagnostic tests, physicians' services, and some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using real-time audio/video technology, instead of requiring their physical presence. In the CY 2021 PFS final rule (85 FR 84538 through 84540), we finalized continuation of this policy through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021. In the March 31, 2020 IFC (85 FR 19246) and in our CY 2022 PFS final rule (see 85 FR 65063), we also noted that the temporary exception to allow immediate availability for direct supervision through virtual presence facilitates the provision of telehealth services by clinical staff of physicians and other practitioners' incident to their own professional services. This is especially relevant for services such as physical therapy, occupational therapy, and speech language pathology services, since those practitioners can only bill Medicare for telehealth services under Medicare telehealth waivers that are effective only during the PHE for COVID–19 (based on the emergency waiver authority established in section 1135(b)(8) of the Act), and for 151 days after the final day of the PHE for COVID–19, as specified by provisions of the CAA, 2022. We noted that sections 1834(m)(4)(D) and (E) of the Act specify the types of clinicians who may furnish and bill for Medicare telehealth services. Outside of the PHE and the 151-day period after the PHE ends, such clinicians include only physicians as defined in section 1861(r) of the Act and practitioners described in section 1842(b)(18)(C) of the Act. We remind readers that after December 31 of the year in which the PHE ends, the pre-PHE rules for direct supervision at § 410.32(b)(3)(ii) would apply. As noted in the CY 2022 PFS final rule (86 FR 65062), this means the temporary exception to allow immediate availability for direct supervision through virtual presence, which facilitates the provision of telehealth services by clinical staff of physicians and other practitioners incident to their professional services, will no longer apply. As such, after the end of the calendar year in which the PHE ends, Medicare telehealth services can no longer be performed by clinical staff incident to the professional services of the billing physician or practitioner who directly supervises the service through their virtual presence.

While we did not propose to make the temporary exception to allow immediate availability for direct supervision through virtual presence permanent, as with last year's rulemaking (86 FR 39149 through 50), we continue to solicit information on whether the flexibility to meet the immediate availability requirement for direct supervision through the use of real-time, audio/video technology should potentially be made permanent. We also solicited comment regarding the possibility of permanently allowing immediate availability for direct supervision through virtual presence using real-time, audio/video technology for only a subset of services, as we recognize that it may be inappropriate to allow direct supervision without physical presence for some services due to potential concerns over patient safety. As discussed in last year's final rule (86 FR 65063), and based on gaps in the currently available evidence, we are in need of more information as we consider whether to make permanent a temporary exception to our direct supervision policy.

We received public comments on expiration of PHE flexibilities for direct supervision requirements. The following is a summary of the comments we received and our responses.

Comment: Commenters offered a variety of perspectives and suggestions for possible ways that CMS could modify the direct supervision requirements. Many commenters that recommended a permanent change to direct supervision rules supported their feedback by raising issues such as health care workforce shortages and concern with clinician burnout that would possibly occur from implementing the pre-PHE direct supervision requirements. Others noted that certain NPPs, such as PAs, and advanced practice nurse practitioners are authorized under state law statutory requirements in many states to practice independently under virtual supervision of a physician. Still others based their recommendations that we establish a permanent virtual direct supervision on a specialty-level or service-level analysis. For example, commenters identified a certain specialty or family of codes that would be typically low-risk for patient safety issues, and indicated that those specialties or services would be appropriate candidates for a permanent virtual direct supervision policy. Some

commenters mentioned that virtual direct supervision may also reduce the burden and overhead costs associated with enrolling their practitioners through multiple MAC jurisdictions.

Response: We continue to gather information on this topic, and we appreciate the information provided by commenters. We remind readers that, as described earlier in this section, our current temporary policy to permit immediate availability for purposes of direct supervision through the virtual presence of the billing clinician was adopted to address the circumstances of the PHE for COVID–19. We believe allowing additional time to collect information and evidence for direct supervision through virtual presence will help us to better understand the potential circumstances in which this flexibility could be appropriate permanently, outside of the PHE for COVID–19. We realize that direct supervision through virtual presence is probably not something that we would have contemplated without our experience in implementing this policy during the PHE, and we hope to learn more about this in the near future. We also note that the Secretary renewed the PHE for the COVID–19 pandemic for a 90-day period beginning on October 13, 2022,[9] which means that the PHE would expire on January 11, 2023, absent any further action by the Secretary regarding the PHE for COVID–19. As such, we expect to continue to permit direct supervision through virtual presence through at least the end of CY 2023 under our previously finalized policy which, as specified in § 410.32(a)(3)(ii), continues through the end of the calendar year in which the PHE ends. With that said, CMS will consider the comments received from the proposed rule for potential future PFS rulemaking.

3. Telehealth Originating Site Facility Fee Update

Section 1834(m)(2)(B) of the Act established the initial Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002, at $20.00, and specifies that for telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The final MEI increase for CY 2023 is 3.8 percent and is based on the most recent historical percentage increase of the 2017-based MEI for the second quarter of 2022.

Therefore, for CY 2023, the final payment amount for HCPCS code Q3014 (*Telehealth originating site facility fee*) is $28.64. The Medicare telehealth originating site facility fee and the MEI increase by the applicable time period are shown in Table 15.

TABLE 15: The Medicare Telehealth Originating Site Facility Fee

Time Period	MEI (%)	Facility Fee for Q3014
Oct. 1, 2001 to Dec. 31, 2002	NA	$ 20.00
2003	3.0	$ 20.60
2004	2.9	$ 21.20
2005	3.1	$ 21.86
2006	2.8	$ 22.47
2007	2.1	$ 22.94
2008	1.8	$ 23.35
2009	1.6	$ 23.72
2010	1.2	$ 24.00
2011	0.4	$ 24.10
2012	0.6	$ 24.24
2013	0.8	$ 24.43
2014	0.8	$ 24.63
2015	0.8	$ 24.83
2016	1.1	$ 25.10
2017	1.2	$ 25.40
2018	1.4	$ 25.76
2019	1.5	$ 26.15
2020	1.9	$ 26.65
2021	1.4	$ 27.02
2022	2.1	$ 27.59
2023	3.8	$ 28.64

[9] *https://aspr.hhs.gov/legal/PHE/Pages/covid19-13Oct2022.aspx.*